AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

24 PRIORITY MEDICAL PRODUCTS AND ROAD-MAP FOR REGIONAL PHARMACEUTICAL MANUFACTURING IN AFRICA REPORT

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Message from the Chief Executive Officer

The African continent stands at a pivotal juncture, with an unprecedented opportunity to harness its potential for sustainable development through regional integration and self-reliance. Health is both a fundamental human right and a cornerstone of economic resilience. As such, the imperative to ensure equitable access to life-saving medical products cannot be overstated.

The 24 Priority Medical Products and Roadmap for Pharmaceutical Regional Manufacturing in Africa report represents the shared vision and commitment of the African Union Development Agency-NEPAD (AUDA-NEPAD) and our stakeholders. The initiative aligns seamlessly with Agenda 2063, Africa's blueprint for transformative development, and reflects our unwavering dedication to achieving health sovereignty across the continent.

The COVID-19 pandemic underscored Africa's vulnerabilities in global supply chains, particularly in the pharmaceutical sector. With 70-80% of the continent's medical needs met through imports, it is clear that dependency on external markets exposes our populations to severe risks. This report not only identifies priority medical products to address Africa's high disease burden but also charts a strategic path toward building a robust, self-reliant pharmaceutical industry.

Our Roadmap emphasises the critical enablers of this transformation: strengthening regulatory frameworks, fostering public-private partnerships, investing in local manufacturing capabilities, and leveraging regional economic communities to drive collaboration. By focusing on high-need, high-impact products, we aim to tackle diseases that disproportionately affect our people while creating economic opportunities across the value chain.

The recommendations in this report reflect the collective wisdom of experts, stakeholders and policymakers from across the continent. Implementing this roadmap will require sustained commitment, innovation and collaboration at all levels. Collectively, we realise a future where Africa meets its own pharmaceutical needs and also contributes to global health resilience.

As we launch this initiative, I invite all stakeholders- governments, Regional Economic Communities, pharmaceutical manufacturers associations, private sector actors, civil society organisations, academia and research institutions and all our development partners to join hands with us in this endeavour.

H,E. Nardos Bekele-Thomas (Mrs)
Chief Executive Officer, AUDA-NEPAD

Acknowledgements

This report, 24 Priority Medical Products and Roadmap for Regional Pharmaceutical Manufacturing in Africa reflects the collective efforts of diverse stakeholders, including representatives from African Union Member States, Regional Economic Communities (RECs), regulatory authorities such as the Food and Drugs Authorities of Ghana and Côte d'Ivoire, the Ivorian Pharmaceutical Regulatory Authority, the African Medicines Agency (AMA), and the Federation of African Pharmaceutical Manufacturers Associations (FAPMA). Partner organizations, including the United States Pharmacopeia (USP), Africa CDC, Clinton Health Access Initiative (CHAI), and UNITAID played a crucial role alongside AUDA-NEPAD, global health organizations, and private sector stakeholders.

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Lastly, we honour the resilience and ingenuity of African pharmaceutical manufacturers, whose work continues to inspire progress toward self-reliance.

This roadmap represents a collective achievement and a shared commitment to securing a healthier future for all Africans.

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Abbreviations and Acronyms

AMA	African Medicines Agency
AMRH	African Medicines Regulatory Harmonisation Initiative
APIs	Active Pharmaceutical Ingredients
AVAREF	African Vaccines Regulatory Forum
BCG	Boston Consulting Group
CVD	Cardiovascular disease
DALYs	Disability Adjusted Life Years
ML	Maturity Level
NCDs	Non-Communicable Diseases
NEPAD	New Partnership for Africa's Development
NMRAs	National Medicines Regulatory Authorities
NRAs	National Regulatory Authorities
NTDs	Neglected Tropical Diseases
PMPA	Pharmaceutical Manufacturing Plan for Africa
R&D	Research and Development
RMNCAH	Reproductive Maternal, Newborn, Child and Adolescent Health
RECs	Regional Economic Communities
SDGs	Sustainable Development Goals
UN	United Nations
UNIDO	United Nations Industrial Development Organisation
WHO	World Health Organisation

GLOSSARY OF KEY TERMS

Active Pharmaceutical Ingredients (APIs): The substances in a drug that are responsible for its therapeutic effect.

Biosimilars: Biologic Medical products highly similar to an already approved reference product, with no clinically meaningful differences in safety or efficacy.

Burden of Disease: This the measure of the impact of diseases and injuries on a population. It combines mortality (death) and morbidity (illness and disability) into a single number. This report has used Disability Adjusted Life Years to measure the burden of disease.

Cardiovascular disease (CVD): Cardiovascular disease covers a wide array of disorders, including diseases of the cardiac muscle and the vascular system supplying the heart, brain, and other vital organs. The most common manifestations of CVD are ischemic heart disease, congestive heart failure, and stroke. CVD is used here as an abbreviation for cardiovascular disease, not cerebrovascular disease.

Clinical Trials: Research studies performed on human participants to evaluate the effectiveness and safety of new medical treatments.

Communicable Diseases: Infectious diseases that can be transmitted from one individual to another, such as HIV/AIDS and malaria.

Disability Adjusted Life Years (DALYs): A measure of the gap in healthy years of life lived by a population as compared with a normative standard. More formally, DALYs are a time-based measure that adds together years of life lost due to premature mortality with the equivalent number of years of life lived with disability or illness.

Drug Molecule: A drug molecule is a specific type of molecule that interacts with a biological target in the body to produce a desired therapeutic effect. They play a crucial role in treating and preventing diseases.

Essential Medicines: These are those that satisfy the priority healthcare needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.

Generic Drugs: Medications that are created to be the same as an existing approved brand-name drug in dosage form, strength, route of administration, quality, and performance characteristics.

Medical products: Encompass a wide range of items and services intended to promote or maintain well-being, including pharmaceuticals, medical devices, dietary supplements, cosmetics, and personal care products.

Ischemic heart disease: A number of heart conditions in which heart muscle is damaged or works inefficiently because of an absence or relative deficiency of its blood supply; most often caused by atherosclerosis, it includes angina pectoris, acute myocardial infarction (heart attack), chronic ischemic heart disease and sudden death.

Local Manufacturing: The production of goods, including pharmaceutical products, within a specific country or local area, aimed at meeting domestic demand.

Market Fragmentation: A situation where the pharmaceutical market is divided into many smaller parts, leading to inefficiencies and coordination challenges among stakeholders.

Market: refers to the pharmaceutical market in Africa, encompassing the supply and demand for medicines, the dynamics of local and international trade, and the interactions between manufacturers, distributors, and consumers within the healthcare system. This report describes the market as the willingness or investment in the procurement of medical products.

Maturity Level (ML): A classification indicating the development stage of regulatory authorities, with levels ranging from 1 (low maturity) to 4 (fully functional).

Medicine Registration: The process through which a pharmaceutical product is approved for use in a specific market, ensuring it meets safety and efficacy standards.

National Medicines Regulatory Authorities (NMRAs): Government agencies responsible for regulating pharmaceuticals, including drug approval and market surveillance.

National Regulatory Authorities (NRAs): Government bodies responsible for the regulation of pharmaceuticals and ensuring compliance with health standards within a country.

Need: refers to the population's requirement for specific drugs and healthcare products to effectively manage and treat health conditions prevalent in the region. This includes the necessity

for accessible and affordable medications to address the high burden of communicable and non-communicable diseases in Africa.

Non-Communicable Diseases (NCDs): Diseases that are not infectious and are often chronic, such as diabetes, cancer, and cardiovascular diseases.

Pharmaceutical Industry: The sector involved in the development, production, and marketing of drugs and medications.

Pharmaceutical Market: The economic arena where pharmaceutical products are bought and sold, influenced by supply, demand, and regulatory frameworks.

Pharmaceutical Manufacturing: This is the process of producing pharmaceutical drugs in accordance with strict quality and safety standards. It involves a complex series of steps, including formulation development, process development, raw material sourcing, production, quality control, packaging, and labelling.

Pharmaceutical Value Chain: Encompasses all the stages involved in bringing a new drug to market, from initial research and development to final distribution and post-market surveillance. It can be broken down into the following key stages: Research & Development (R&D), Clinical Trials, Regulatory Approval, Manufacturing & Production, Marketing & Sales, and Post-Market Surveillance.

Priority Medical Products: Essential medical products are identified as critical for addressing specific health needs and improving health outcomes in a population, often based on disease burden and local health priorities. These include diagnostics, therapeutics, vaccines, sundries, and medical devices. This report has listed specific drug molecules as priority medical products without going into details of formulation and strength for some molecules as this may result in multiple products for a single molecule.

Public-Private Partnerships: Collaborations between government entities and private sector companies aimed at improving services and products, especially in healthcare.

RECs (Regional Economic Communities): These are regional groupings of African states and are the pillars of the AU. These facilitate regional economic integration between members of the individual regions and through the wider African Economic Community (AEC).

Regional Manufacturing: The production of goods by facilities located in a specific region, often serving multiple countries within that area to enhance supply chain efficiency.

Regulatory Harmonization: The process of aligning regulatory standards and practices across countries to facilitate trade and ensure safety.

Regulatory Oversight: The process of monitoring and enforcing compliance with laws and regulations governing pharmaceuticals and healthcare products.
Research and Development (R&D): The process of innovating and developing new drugs and therapies to address specific health needs.

Stroke: Stroke is defined as a condition that results in a disruption of blood flow to a region of the brain causing irreversible “death” of brain tissue. There are two main types of strokes: hemorrhagic and ischemic. Stroke is the main cause of mortality and burden for cerebrovascular disease.
Sustainable Development Goals (SDGs): A collection of 17 global goals set by the United Nations to address various global challenges, including health and well-being.

WHO Prequalification Scheme: A program by the World Health Organization that evaluates applications from manufacturers to determine whether their products meet its standards of quality, safety, and efficacy.

Executive Summary

Background

Africa is the world's second-most populous continent with approximately 1.4 billion people, representing about 17% of the global population. Africa carries 25% of the world's global burden of disease yet contributes 3% of the worldwide medicine manufacturing. The continent accounts for a quarter of global vaccine demand but produces 0.1% of the world's vaccine supply.

The COVID-19 pandemic exposed Africa's vulnerability to disruptions in global pharmaceutical supply chains, underscoring the urgent need to strengthen local and regional manufacturing capacities. The crisis highlighted the critical importance of the Pharmaceutical Manufacturing Plan for Africa (PMPA), a framework developed to guide the continent toward a self-reliant, sustainable, and competitive pharmaceutical industry capable of meeting public health needs.

Aligned with Agenda 2063's Second Ten-Year Implementation Plan, which emphasizes industrialisation, human development, and health security as key pillars for achieving the "Africa We Want," the PMPA serves as a strategic vehicle to reduce Africa's dependence on imported medicines. The plan envisions a robust pharmaceutical sector that fosters regional integration, enhances access to quality and affordable medicines, and ensures resilience against future health crises.

In support of the PMPA, AUDA-NEPAD launched the 24-priority medical products list and an accompanying roadmap for regional manufacturing as practical steps toward achieving self-reliance in the African pharmaceutical industry. These initiatives focus on scaling up the local production of essential medicines, vaccines, and health products that are critical to public health, particularly in light of Africa's growing population and disease burden.

The roadmap aims to address the structural, regulatory, and financial challenges impeding pharmaceutical manufacturing on the continent. It also seeks to foster collaboration among Member States, Regional Economic Communities (RECs), and the private sector to build a resilient pharmaceutical manufacturing ecosystem.

Objectives

2. To provide a strategic guide to pharmaceutical manufacturing stakeholders on areas that require focused investments to spur the development of the sector.
3. To guide policymakers at continental, RECs and national levels on priority medical products to provide incentives to in order to achieve greater health and economic impact.
4. To provide policymakers and pharmaceutical manufacturers with insights into products with specific supported projects to strategically leverage these resources to accelerate their own efforts and contribute to the growth of regional pharmaceutical production.

5. To maximize the benefits of supportive global health initiatives, take advantage of current available opportunities, identify synergies and remove any duplication of efforts in pharmaceutical manufacturing on the continent.

Methodology

The **24-priority medical products list and a roadmap** were developed using existing/ secondary literature followed by wide expert stakeholder consultations across different regional economic communities. The primary consideration was public health needs, taking the top ten disease burden on the continent. An options analysis of need and market was then conducted before selected medicines were subjected to pharmaceutical ecosystem considerations for medicines that scored best on a traffic lights assessment of feasibility/ capacity to manufacture, absence of Intellectual Property Rights barriers, availability of technology transfer, availability of inputs, regulatory readiness, economic viability of products, availability of political support, pooled market, availability of supportive global health initiatives among others.

Key findings

The report presents an analysis of medical products required to manage the top disease burdens in Africa. It identifies key challenges hindering local pharmaceutical manufacturing and proposes strategies to enhance its capacity and sustainability.

Manufacturing challenges: Current local manufacturing capabilities are limited, with many essential products heavily reliant on imports. Key challenges include inadequate infrastructure, limited access to technology, and insufficient human capital.

Enabling factors: To foster local pharmaceutical manufacturing, the report recommends strengthening regulatory frameworks, investing in research and development, improving access to raw materials, facilitating market access, addressing intellectual property rights, enhancing human capital development, and fostering public-private partnerships.

The essential priority medical products selected encompass a wide range of medicines from antibiotics and antiretrovirals to medical devices and diagnostics. The 24 priority medical products selected to address Africa's major disease burden have been divided into six categories below:

A. Highneeds Highmarket

1. Antibiotics: Amoxicillin
2. Pain management: Paracetamol
3. HIV/ AIDS: HIV tests, Cabotegravir, Tenofovir + Lamivudine + Dolutegravir (TLD)
4. Antimalarials: mRDTs, Artemether + lumefantrine, Sulfadoxine-pyrimethamine
5. TB: Bedaquiline

B. Growing need high market

6. Stroke: Atorvastatin
7. Injuries: Intravenous fluids
8. Diabetes: Insulin analogues, Metformin
9. Ischemic Heart Disease/ Hypertension: Amlodipine, Valsartan

C. Low need high market

10. Cancer: Docetaxel

D. High need Low market

11. Maternal health: Oxytocin, Misoprostol, Magnesium sulphate
12. Newborn: Birth asphyxia and birth trauma- Medical Oxygen
13. Child health: Antidiarrheals: Oral rehydration salts + Zinc sulphate, Rotavirus vaccine

E. Growing need low market

14. Sickle cell disease: Hydroxyurea

F. Low need low market

15. NTDs: Praziquantel

Six additional molecules: Tranexamic acid, heat-stable carbetocin, condoms, HIV Vaccine, Malaria Vaccine, HBV vaccine have been proposed for future consideration. The list should be reviewed routinely and every five years in line with changing epidemiological patterns.

Key recommendations include:

- Prioritise high-need, high-market products: Focus on manufacturing drugs for infectious diseases and non-communicable diseases with significant burdens.
- Invest in Research and Development (R&D): Support local innovation and collaborate with international partners. The African Union should consider the development of a self-sufficient, pan-African R&D system that addresses evolving public health issues. The key to this is to harness the untapped power of collaboration among African researchers by forming and supporting networks of research groups in Africa.
- Strengthen regulatory frameworks: Harmonize regulations and build the capacity of regulatory authorities. There is a need for African countries to systematically apply policy regulations that level the playing field. This would enable local manufacturers to compete with their international counterparts.
- Improve access to raw materials: Promote local production of APIs and explore alternative sourcing options.
- Facilitate market access: Create a conducive economic environment and establish regional manufacturing hubs. To ensure guaranteed markets, national and regional procurement laws should consider allocating percentage points for local producers, if the quality of the products is deemed to be of the required standards
- Address intellectual property rights barriers: Optimize IPR policies to balance innovation and access.
- Enhance human capital development: Invest in education and training.
- Foster public-private partnerships: Collaborate with multinational companies and development partners. The ongoing initiatives to promote regional pharmaceutical manufacturing in Africa offer a significant opportunity to strengthen value chains and improve access to affordable medical products.
- Improve infrastructure and logistics: Invest in infrastructure and enhance supply chain management.
- Incentives: Governments should induce

investment through incentives that lower the cost or risk for the investor, or both. Use of trade policies in a strategic way is another approach that Governments could support the importation of raw materials and capital goods.

By implementing these recommendations, Africa can significantly strengthen its local pharmaceutical manufacturing capabilities, improve access to essential medicines, and contribute to the continent's economic development.

A five-year roadmap, with an estimated cost of USD 18,157,500, has been proposed for AUDA-NEPAD to implement the priority list of medical products. The roadmap aims to establish a self-sufficient, sustainable, and resilient pharmaceutical manufacturing ecosystem in Africa, enabling the continent to meet at least 50% of its pharmaceutical needs locally.

1. INTRODUCTION

1.1 Background

1.1.1 Disease burden in Africa

Africa is the world's second-most populous continent, home to approximately 1.4 billion people as of 2023, representing about 17% of the global population[1]. The continent is experiencing rapid population growth, with projections showing that it will double by 2050, adding 1.2 billion people to the current population[2,3].

Africa carries a disproportionate share of the world's global burden of disease, estimated at 25%[4]. The continent is currently grappling with a triple burden of communicable diseases, non-communicable diseases (NCDs), and injuries and trauma[5].

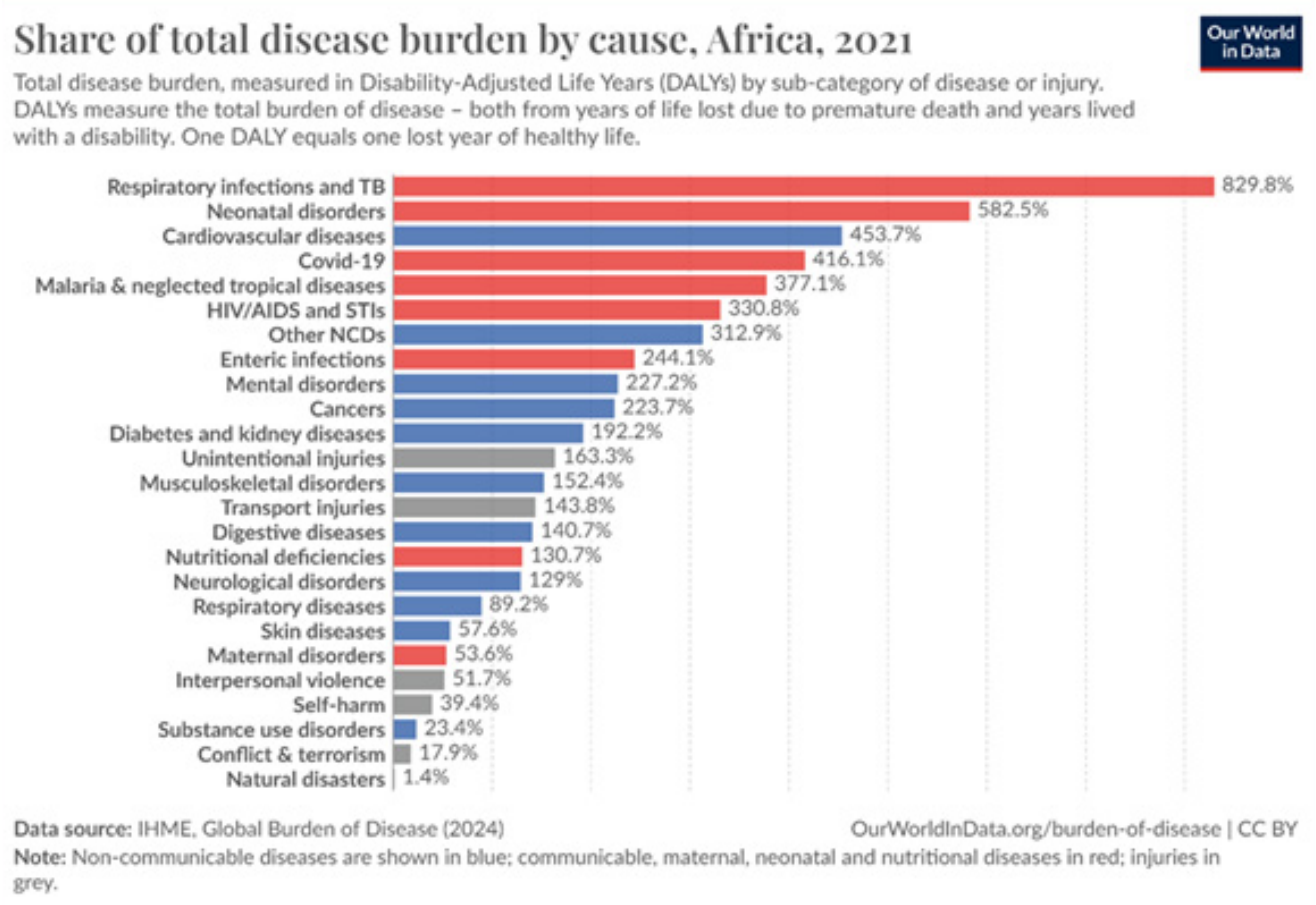


Figure 1: Disease burden in Africa

Source: Max Roser, Hannah Ritchie and Fiona Spooner (2021)[6]

Sub-Saharan Africa remains the epicenter of the HIV/AIDS epidemic globally, accounting for 75% of HIV/AIDS cases[7]. In 2022, the WHO Africa Region was home to 94% of malaria cases (233 million) and 95% (580,000) of malaria deaths[8]. Children under 5 accounted for about 80% of all malaria deaths in the region [9]. Just over half of all malaria deaths globally occurred in four African countries: Nigeria, which accounted for 26.8%; the Democratic Republic of Congo at 12.3%; Uganda at 5.1%; and Mozambique at 4.2%[10]. Africa has the highest incidence and mortality rates for tuberculosis (TB) worldwide, with nearly 2.5 million people falling ill and 424,000 lives lost in 2022[11].

Sub-Saharan Africa has seen a rapid increase in non-communicable diseases (NCDs) over the last decades. The proportion of all disability-adjusted life years (DALYs) attributable to NCDs rose from 19% to 30% of the total burden between 1990-2017[12]. Africa experiences a significantly greater burden of injury and trauma compared to other regions [13]. In fact, sub-Saharan Africa has the highest incidence of road traffic fatalities globally[14].

Outbreaks like Yellow Fever, Cholera, Ebola and Mpox (formerly known as monkey pox), along with natural and human-made disasters, are having a detrimental impact on Africa and pose ongoing threats to the continent's development goals[15,16].

1.1.2 The Pharmaceutical Industry in Africa

Africa's pharmaceutical industry is still in a nascent stage, compared to global powerhouses like India and China. China and India's pharmaceutical industries hold a market share of about USD 120 billion and USD 19 billion, respectively while the whole of Africa holds a market of USD 65 billion[17].

Africa contributes 3% of the global medicine manufacturing[18] with a staggering 70%-80% of its pharmaceutical needs being met through imports[19]. About 75% of Africa's pharmaceutical imports are from the European Union, India, and China[20]. Countries like South Africa and Morocco have achieved a degree of self-sufficiency, producing 70-80% of their own medicines[21], while some central African countries rely almost entirely on imports, importing nearly 100% of their pharmaceutical requirements[22].

Approximately 375 drug companies operate in Africa, primarily in North Africa. In Sub-Saharan Africa, manufacturers are clustered in just nine out of 46 countries, according to a 2019 McKinsey report[23]. Currently, only Kenya, Nigeria, and South Africa have established pharmaceutical industries in Sub-Saharan Africa. These countries produce medicines primarily for their own populations and also export to neighbouring markets[24].

Additionally, local pharmaceutical companies in sub-Saharan Africa focus on downstream processes of the value chain. They source active pharmaceutical ingredients (APIs) from external manufacturers to create finished products. Africa's pharmaceutical production primarily focuses on generic drugs, which account for about 70% of total outpu[25]. Around a hundred manufacturers in sub-Saharan Africa focus solely on repackaging

bulk drugs for consumer sale[26]. As of 2020, there were 85 local production sites, with an average production capacity of 250-300 million units,[27] these currently meet about 27% of the continent's demand.

Despite accounting for a quarter of global vaccine demand, Africa mostly relies on imported vaccines as the continent produces 0.1% of the world's vaccine supply[28]. Currently, Senegal's Institut Pasteur de Dakar is the sole WHO-prequalified vaccine manufacturer in Africa, producing yellow fever vaccine[29]. Figure 2 is a map below depicted the location of pharmaceutical manufacturers in Africa.

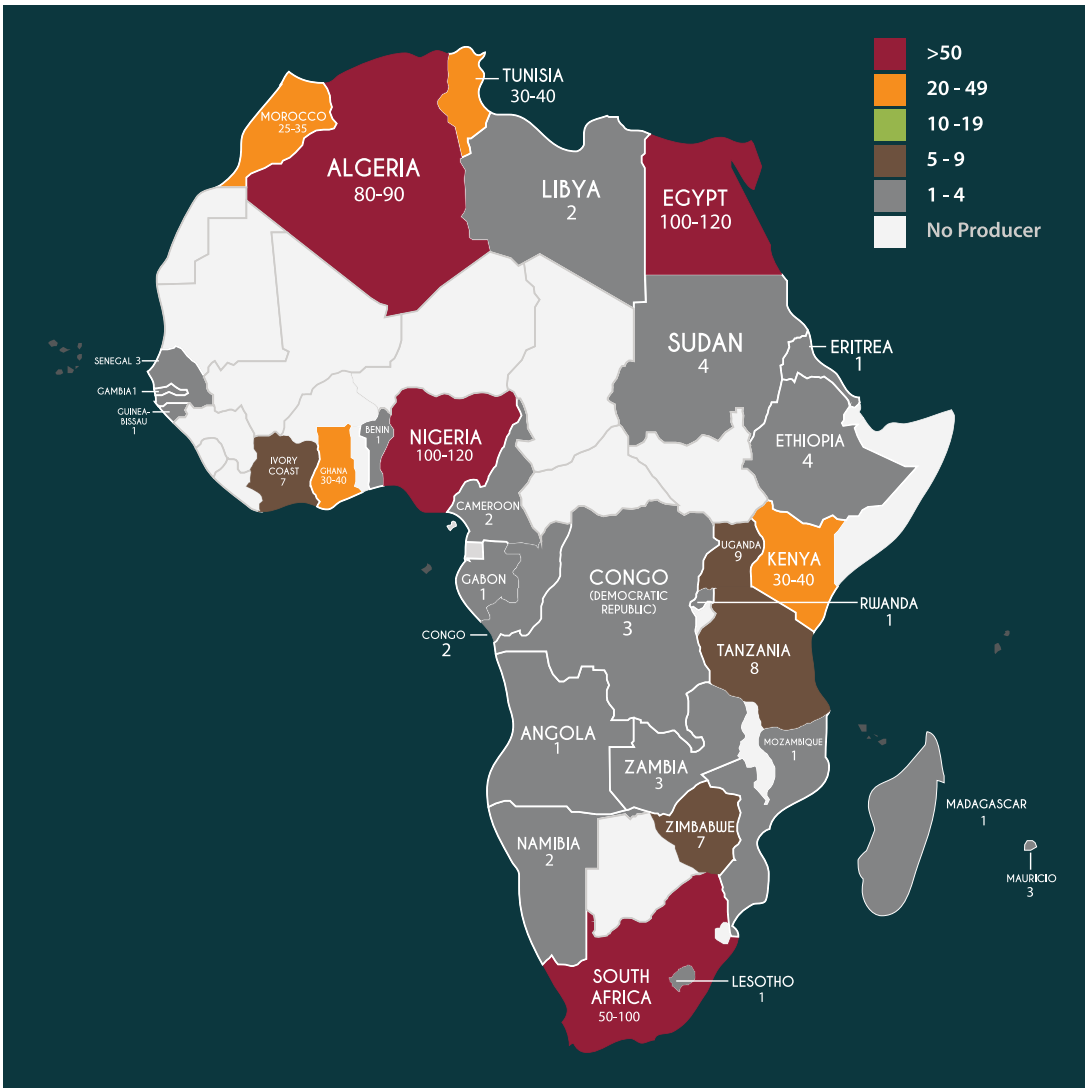


Figure 2: Number and location of pharmaceutical manufacturing plants in Africa

Source: African Development Bank Group, 2022. A New Frontier for African Pharmaceutical Manufacturing Industry

The sustainability of Africa's pharmaceutical industry is fragile due to its heavy reliance on imported raw materials and finished products. This dependency raises concerns about self-sufficiency, as it impedes local production and creates vulnerabilities in the supply chain. Additionally, a lack of investment in research and development restricts innovation and the development of new products essential for addressing local health needs[30]. Additionally, fragmented efforts among stakeholders lead to inefficiencies, missed opportunities for collaboration, and duplication of initiatives, further compromising the industry's sustainability[31].

Many African National Regulatory Authorities (NRAs) are at low maturity levels, limiting their effectiveness in regulating local pharmaceutical manufacturing and hindering sustainable growth[32]. A shortage of qualified personnel and inadequate training further undermine the industry's effectiveness and sustainability [33].Ethiopia has emerged as a leading example of pharmaceutical development in Africa. The country has invested significantly in building its domestic pharmaceutical industry, aiming to improve access to affordable and quality medicines[34].

Through the Ethiopian Pharmaceutical Manufacturing Development Program, formally known as the National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015–2025), the Federal Government of Ethiopia, with support from World Health Organization (WHO), the European Commission, the Bill & Melinda Gates Foundation and foreign investors, is investing in quality local production by implementing a Good Manufacturing Practices (GMP) roadmap; strengthening the national medicines regulatory system; and encouraging cluster development and production APIs[35]. A key milestone was the local production of a new-generation antibiotic, which has been incorporated into public health services. This achievement highlights Ethiopia's commitment to pharmaceutical self-sufficiency[36].

1.1.3 Pharmaceutical Regulatory Capacity in Africa

Africa is home to 54 national medicines regulatory agencies (NMRAs), and their capabilities differ greatly, with the majority unable to carry out essential tasks[37]. The WHO reports that only 7% of African nations possess moderately developed capacities, while more than 90% have either minimal or no capacity at all[38]. Most NMRAs in Africa operate at low maturity levels, with many at maturity level 1 (ML1)[39]. Only a few countries; Egypt, Ghana, Nigeria, South Africa, Tanzania, Zimbabwe, (and most recently Senegal and Rwanda) have achieved maturity level 3 (ML3), which is necessary for effective regulatory oversight and the ability to provide approvals for local manufacturers[40]. None have reached maturity level 4 (ML4), which designates a fully functional and robust regulatory system[41].

The regulatory environment in Africa is fragmented, with various stakeholders working independently, leading to inefficiencies and inconsistent practices across the continent[42] . Additionally, many NMRAs do not meet international standards, hindering local

manufacturers' access to global markets[43]. The weak medicines regulatory systems in Africa, which suffer from unclear policies and fragmented legal frameworks contribute to the continent's challenges of poor-quality medicines, with an estimated 18.7% of medicines deemed substandard or falsified [44]. Issues like high staff turnover and a lack of qualified regulatory professionals in NMRAs continue to exist, along with insufficient regulatory infrastructure and ineffective collaboration between these agencies at the regional level[45,46].

Africa's regulatory landscape also faces challenges concerning medicine registration, that is, the regulation of biosimilars, vaccines, health product advancements, clinical trials, blood products, and medical devices, particularly diagnostics[47,48]. The regulatory approval process in sub-Saharan Africa is notoriously slow. Even well-resourced regulatory agencies often take approximately four to seven years to approve new medicines[49,50]. This is due to lengthy registration processes, resource constraints, and inadequate use of reviews from stringent regulatory bodies[51].

Ethiopia is making positive strides. Despite having a pharmaceutical market valued at around USD 600 million, the regulator's budget is about USD 6.6 million, which is a relatively higher proportion compared to larger markets in Brazil, and Turkey[52].

To address the shortcomings of Africa's regulatory landscape, several national, regional, and global initiatives aimed at enhancing pharmaceutical and vaccine manufacturing initiatives have been established. These include the African Vaccines Regulatory Forum (AVAREF), the African Medicines Regulatory Harmonization Initiative, the Network of Official Medicines Control Laboratories, and the African Medicines Agency (AMA). Additionally, the WHO Prequalification Scheme offers support. Collectively, these initiatives aim to strengthen regulatory capacities across the continent[53].

1.1.4 Challenges and Opportunities of the African Pharmaceutical Industry

Challenges

Regulatory and institutional hurdles: Many African countries grapple with weak regulatory frameworks. NMRAs cannot often efficiently oversee local manufacturing. This hinders the approval of new drugs and compliance with global standards. Furthermore, inconsistent government funding for NMRAs hampers their ability to support local production.[54]

Financial and infrastructure constraints: Local pharmaceutical manufacturers face significant financial challenges, including limited access to capital and reliance on inconsistent government funding. The manufacturing infrastructure is often inadequate, with shortcomings in facilities for clinical trials and modern production technologies. This hinders the production of high-quality pharmaceuticals.[55]

Supply chain and market challenges: Heavy dependence on imported raw materials and finished products creates vulnerabilities in the supply chain . This limits the ability to meet local demand and can lead to drug shortages. Additionally, the fragmented pharmaceutical

market, characterized by a lack of coordination among stakeholders, hampers efficiency and collaboration.[57]

Innovation and human capital limitations: Insufficient investment in research and development (R&D) stifles innovation within the local pharmaceutical sector, hindering the development of new drugs to address specific health needs.[58]A shortage of skilled personnel and inadequate training further impede the industry's growth.[59]

Policy and environmental factors: Unfavourable legal and policy environments, often designed to protect multinational pharmaceutical companies, create barriers for local manufacturers. These barriers hinder knowledge sharing and technology transfer.[60] Political instability in some regions also exacerbates challenges for local businesses.

Collaboration and partnership gaps: A lack of strategic partnerships between governments, manufacturers, and other stakeholders hinders resource mobilization and knowledge sharing. Stronger collaboration is essential to overcome these challenges and foster the growth of the local pharmaceutical industry.[61] Africa's pharmaceutical sector is too complex for any single nation or organization to handle alone. To achieve self-sufficiency in medicine, countries must collaborate and share resources. Isolation will hinder Africa's efforts to control its own pharmaceutical industry.[62]

Opportunities

Growing demand for local production: There is an increasing recognition of the need for local pharmaceutical production, especially in light of recent global health crises.[63]This demand creates opportunities for local manufacturers to fill gaps in the supply of essential medicines and vaccines.

Public-private partnerships: Opportunities exist for public-private partnerships that can mobilize resources, expertise, and technology. Collaborations between governments, local manufacturers, and private sector entities can drive innovation and improve manufacturing capabilities. [64]

Regional cooperation: Enhanced regional cooperation among African countries can facilitate knowledge sharing, resource pooling, and collaborative initiatives.[65] This can help create a more integrated pharmaceutical market and improve access to medicines across the continent. The African Continental Free Trade Area (AFCFTA) agreement is expected to boost intra-African trade and reduce reliance on imports[66].

Support from international organizations: Various international organizations, including the WHO, African Union Development Agency (AUDA), Africa CDC and others, are advocating for increased investment in local manufacturing. This support can lead to funding opportunities and technical assistance for local manufacturers.[67]

Focus on research and development: There is a growing emphasis on investing in research and development (R&D) tailored to the continent's specific health needs. This focus can lead to the development of innovative products that address local diseases and conditions, enhancing the competitiveness of

local manufacturers.[68] One such initiative if the BRILLIANT (BRinging Innovation to cLinical and Laboratory research to end HIV In Africa through New vaccine Technology) Consortium, led by African scientists, comprises a multi-disciplinary collaboration from Nigeria, Uganda, Kenya, Tanzania, Zimbabwe, Zambia, Mozambique, and South Africa. The consortium aims to build the capacity of HIV vaccine R&D in sub-Saharan Africa, with the overall objective of developing and evaluating HIV vaccine candidates emanating from the continent.[69]

Increased public funding: There is potential for increased public funding for health and pharmaceutical sectors, especially as governments recognize the importance of health security.[70] This funding can support local manufacturing initiatives and infrastructure development.

Regulatory harmonization: Efforts to harmonize regulatory frameworks across African countries such as AMA can simplify the approval processes for local manufacturers[71]. This can facilitate easier access to markets, ensure quality and encourage investment in local production.

Sustainable Development Goals (SDGs): Aligning local manufacturing efforts with the United Nations Sustainable Development Goals can attract funding and support from international donors and organizations committed to improving health outcomes in Africa[72].

1.2 Justification and rationale for a priority list

1.2.1 African Union Commitment

African leaders recognized their countries' health plight and in 2001, adopted the Abuja Declaration, which among other commitments, mandated all African Union member states to allocate 15% of their national budget toward strengthening healthcare[73]. This has led to an increase in total healthcare expenditures in most African countries, with improved health outcomes[74]. However, the improvements have remained slow and have been heavily dependent on external support[75]. Moreover, despite the push for country-level health financing and localization for self-sustainability, the majority of the market for ARVs is controlled by international donors – 80% of ARVs are imported[76].

Scaling up the weak and limited local production of pharmaceuticals in Africa is essential in tackling local epidemics of common communicable and non-communicable diseases[10,77]. Africa Agenda 63 aspires to transform the continent through inclusive and sustainable economic growth and development and is aligned with the SDGs[78]. The first 10 years of Agenda 63 until 2023 were for convergence on: improved standards of living; transformed, inclusive and sustained economies; increased levels of regional and continental integration; a population of empowered women and youth and a society in which children are cared for and protected; peaceful societies, demonstrate good democratic values and practice good

governance principles and which preserve and enhance Africa's cultural identity[79]. The second 10 year-phase targets acceleration.

Regional pharmaceutical manufacturing is an answer to Agenda 63 outcomes as it not only improves public health security but also contributes to the economic growth of the population while building resilience against inequalities in the supply of health commodities in Africa that were greatly exposed during the COVID-19 pandemic.

Recognizing the need to bolster the continent's pharmaceutical capabilities, Decision 55 was adopted to develop the Pharmaceutical Manufacturing Plan for Africa (PMPA) within the framework of the New Partnership for Africa's Development (NEPAD) which had been established five years earlier, in 2001. Subsequently, in 2007, heads of state endorsed the PMPA as a framework to not only increase the production of essential HIV drugs but also to promote the manufacturing of other vital medicines to address Africa's disproportionately high disease burden.

AUDA-NEPAD initiated efforts in 2009 to cultivate a robust pharmaceutical sector by supporting regional economic communities in establishing mechanisms for harmonizing medicines regulation through the African Medicines Regulatory Harmonisation Initiative (AMRHI). This endeavour aimed to ensure the quality, efficacy, and affordability of both locally manufactured and imported products. In 2012, the PMPA business plan, endorsed alongside the decision to establish the African Medicines Agency, outlined strategies to address key challenges facing the African pharmaceutical industry. The subsequent years witnessed Africa grappling with emerging public health threats[80], prompting a renewed commitment to bolstering the continent's capacity to respond to emergencies thus accelerating the establishment of two major institutions the Africa CDC and AMA. Furthermore, the adoption of the Model Law on Medical Products Regulation in 2016 provided a crucial legal framework to regulate medicines circulating in African markets, safeguarding public health against substandard and falsified products. Subsequently, in 2019, the treaty for the establishment of the African Medicines Agency (AMA) came into force, further solidifying efforts to enhance pharmaceutical regulation and coordination on the continent.

1.2.2 Rationale

The COVID-19 pandemic exposed Africa's vulnerability to disruptions in pharmaceutical supply chains[81]. Moreover, manufacturers in the sub-Saharan region rely almost 100% on imported raw materials[10] and therefore lockdowns affected the ability to source raw materials[82]. The pandemic emphasized the case for scaling up regional manufacturing[83]. Since the COVID-19 pandemic, the African manufacturing effort has gained momentum strongly. At the latest count, 30 manufacturing projects in 14 countries have been announced, supplementing the facilities that already exist. While this flurry of announcements testifies to a strong commitment to scaling up manufacturing, it also gives rise to **strategic concerns – notably, the need for coordination**. It is imperative that manufacturing projects align with the strategic priorities of global, continental and regional ongoing initiatives to enhance

local production in order to prevent economic failures and wasted investments.

With the increased push for local pharmaceutical manufacturing on the African continent[84], local manufacturers have expressed a concern over which products to prioritise[85]. They suggest that the mechanisms would best be developed by a continental organisation which could facilitate coordination by setting up forums, centralising and disseminating information, providing market intelligence, and identifying strategic areas in alignment with mid- and long-term global priorities.

AUDA-NEPAD leads initiatives to strengthen regional manufacturing capabilities for essential medical products, including therapeutics, vaccines, diagnostics, and medical devices. These efforts aim to improve public health outcomes, reduce dependence on imports, and stimulate job creation along the manufacturing value chain.

Lessons can be drawn from some African countries that have achieved pharmaceutical self-sufficiency and from several countries such as China, India and Indonesia as well as from initiatives at the continental level and at regional economic communities.

1.2.3 Examples of pharmaceutical production self-sufficient countries in Africa

Tunisia

Tunisia is a growing pharmaceutical powerhouse. The World Bank Group's 2014 assessment of Tunisia's pharmaceutical sector highlighted that it has experienced very strong growth, with an average annual rate of 15% – much higher than the global average[86]. The assessment denotes that the pharmaceutical sector has grown by more than 45% over the 2014-2018 period[87].Tunisia's pharmaceutical sector is composed of 119 companies as of 2017, including 33 units dedicated to the production of drugs for human use[88]. These companies meet 49% of the country's demand for medicines, primarily through the production of generics, and employ over 6,000 people, with 38% of those being highly skilled, high-salary positions[89]. The country's pharmaceutical exports have also grown, with the share increasing from 10% in 2014 to more than 17% in 2018 [90]. Tunisia has benefited from its geographical proximity to Europe, and the country has signed advantageous free trade agreements with countries in sub-Saharan Africa, the Middle East, and the European Union[91].

One of the main assets of the Tunisian pharmaceutical market is the competitively low cost of labour. The average annual cost of a Tunisian engineer is highly competitive compared to other major destinations and the same applies to operators and technicians in the sector[92].

Tunisia's pharmaceutical sector also benefits from a rich ecosystem, including the presence of R&D centres. This promotes scientific progress and the development of industry clusters[93]. The government set up a development program for industrial parks, aligning with its national strategy for regional development. Tunisia has over 150 industrial parks covering more than 10,000 hectares. The average price for land in current sales is around 12 euros per square metre. The government has a 2016-2020 program to develop over 65 new industrial parks spanning over 2,000 hectares. There is also a renovation program for 60 existing industrial parks covering over 1,500 hectares[94].

The pharmaceutical sector aims to maintain local production growth above 8% annually. It targeted creating over 4,000 additional jobs by 2023. The goal was to increase local manufacturing's share of total pharmaceutical industry coverage from 52.5% to 62% by 2023. Ten additional manufacturing units were planned to start operations by 2023 and exports were targeted to grow from 17% to 30% (520 million dinars) by 2023. Direct investment (local and foreign) was planned to increase from 720 million to 1,400 million dinars by 2023[95].

South Africa

South Africa has a well-developed manufacturing sector, including facilities for producing biotechnology products. The country also has strong R&D capabilities, particularly in the medical and healthcare industries[96].

In 2021, South Africa's pharmaceutical market was worth USD 4.6 billion and is expected to expand at a rate of over 4% per year from 2022 to 2026[97]. The medical devices market in South Africa was valued at USD 3.6 billion in 2021, and is projected to grow at a rate of over 4% per year from 2022 to 2027[98]. The key segments of the South African pharmaceutical market are generics, biologics, biosimilars, and over-the-counter (OTC) drugs[99].

In 2013, generics accounted for 63% of the private pharmaceutical market and 80% market share in the government's pharmaceutical use[100]. The value of locally manufactured pharmaceuticals exported in 2015 was USD 360 million[101].

South Africa's pharmaceutical and medical device sectors are the largest and most advanced in sub-Saharan Africa. Pharmaceutical and medical device sales have more than doubled in the last 10 years and were expected to reach USD 3.2 billion and USD 1.3 billion, respectively, in 2019[102].

The private health sector absorbs about two-thirds of pharmaceutical output, while the public health sector accounts for the remaining one-third[103]. Of the 265 South African pharmaceutical manufacturers, more than half exclusively supply the private sector, 10% exclusively supply the public health sector, and the remaining companies supply both sectors[104].

South Africa is the sole member of the Southern African Development Community (SADC) that meets the WHO's Good Manufacturing Practice standards. This places South Africa in a strategic position as a gateway for pharmaceutical manufacturers to access the broader southern African market[105].

1.2.4 What is a priority medical products' list?

Priority medical products list is not a new phenomenon and has been used by countries to prioritize not only healthcare needs but also improve local pharmaceutical manufacturing and procurement. The most common priority list is the essential medicines list which is based on the most pressing healthcare needs of a population. Below are examples of priority lists.

The essential medicines list

There are numerous medicinal products in the market and it is vital to have selective considerations for the health needs of the majority of the population and also to guarantee the safety, efficacy, and cost-effectiveness of the medical products. The essential medicines approach is an example of the prioritization of a medical productslist which is reasonable, well organized, and based on sound ethics and economics[106].

The concept of essential medicines is influenced by both demand and supply. While public healthcare facilities primarily meet the medical needs of people from low socioeconomic backgrounds, the development and availability of these medicines are largely driven by market forces[107]. Private sector market forces prioritize medicines with high return on investment and sales targets, often neglecting essential medicines due to lower profit margins. This market-driven focus limits the availability of essential medicines[108,109].

The concept of a priority list of medicine has existed for over 54 years with Tanzania making their first Essential Medicine List in 1970, and WHO publishing their first list of Essential Drugs in 1977[110]. The WHO's list of essential medicines emphasizes the importance of prioritizing certain medications over others based on the realization that many essential drugs in developing countries were often unavailable to those who needed them[111]. The WHO's list of essential medications has been a subject of intense debate[112]. Pharmaceutical companies have criticized it for being overly restrictive[113], while advocacy groups, particularly those focused on HIV and AIDS, have accused it of neglecting crucial medicines[114]. The process of selecting medicines has undergone significant changes, moving from relying on experience to using evidence-based methods[115].

Essential medicines are those that satisfy the priority healthcare needs of the population. They are selected based on public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. These are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford[116].

The structure of the WHO model EML is divided into two categories: Core, defined as efficacious, safe, and cost-effective medicines for priority conditions (selected on the basis of current and estimated future public-health relevance and potential for safe and cost-effective treatment); and Complementary, defined as "medicines for priority diseases which are efficacious, safe and cost-effective but not necessarily affordable, or for which specialized health care facilities or services may be needed" [117].

The WHO releases a model list of essential medicines every two years, featuring medications considered vital for all healthcare systems[118]. This list serves as a reference for countries and organizations to create their own tailored national and institutional essential medicines lists and policies based on their specific requirements[119]. The model list provides guidance to governments, health facilities and procurers on which medicines are the best value in terms of benefits for individuals and communities.[120]

Restricted Lists

Some African countries have restricted the importation of particular pharmaceuticals in order to promote local pharmaceutical manufacturing.
The Ghanaian pharmaceutical sector's strength has been driven by government incentives that aim to promote local production, that is[121]:

- *Banning the import of 44 medicines that could be manufactured locally or required regulation due to health concerns.*
- *Exempting 66 out of the 200 basic materials required for production from import duty.*
- *Introducing various tax incentives.*

These measures have resulted in significant growth of the industry, with the share of local production increasing from 10% to 30% and the number of local manufacturers increasing from 9 in 1989 to 39 in 2014[122].

Algeria implemented import restrictions in February 2021 to boost local pharmaceutical manufacturing, saving EUR 800 million on imports[123]. Imports were limited to only essential products not manufactured locally or in insufficient quantities[124].

The East African Community (EAC) implemented a tariff structure in 2005 that aimed to incentivize local production including pharmaceuticals. Raw materials and capital goods were subject to a 0% tariff, intermediate goods faced a 10% tariff, a 25% tariff was applied to final/consumer goods, and a 35% for imported finished products available in the region[125].

There are also country-specific restrictive policies aimed to foster local production. For example, the 2014 “Buy Uganda Build Uganda” policy, approved by the Ugandan government to promote local manufacturing, including pharmaceuticals. The policy led to the development of a restricted list of 32 medicines for local production which attracted an extra importation levy of 10% and also allowed a 15% price preference for local suppliers in public procurements, aimed at boosting domestic small/ medium industries[126].

To strengthen regional pharmaceutical manufacturing in Africa, it is crucial to focus on producing essential medicines that align with the region’s specific health needs and priorities. By prioritizing these products, countries can enhance their self-sufficiency, reduce reliance on imports, and improve access to affordable and quality healthcare for their populations.Why does Africa need a priority medical products list?

Africa needs a priority list of medical products for regional manufacture for several reasons:

1)	Africa relies heavily on imports from Asia, Europe, or America exposing the continent to supply chain disruptions. The COVID-19 pandemic highlighted vulnerabilities in global supply chains, where many countries faced shortages of critical medical supplies. Regional manufacturing can mitigate these risks, ensuring a more stable and reliable supply of essential medical products.
2)	Africa faces unique health challenges, including a high prevalence of infectious diseases like malaria, tuberculosis, and HIV/AIDS, as well as emerging non-communicable diseases. Locally manufacturing prioritized medical products tailored to these specific health needs can enhance the responsiveness and appropriateness of healthcare delivery.
3)	Developing a regional pharmaceutical industry can stimulate economic growth, create jobs, and build local expertise. It can also reduce dependency on foreign aid and imports, fostering a more self-reliant and sustainable healthcare system.
4)	Regulatory and Quality Control: While importing from established markets ensures high standards, regional manufacturing can be equally regulated. By developing local capacity and regulatory frameworks, African countries can maintain high standards of production and quality control, ensuring safe and effective medical products.

5)	A priority list of medical products serves as a strategic guide, focusing investments and resources on products that have the greatest impact on public health. By identifying and prioritizing these critical medications, initiatives can be more effectively aligned with the continent's specific needs, ensuring that efforts are not spread too thin.
6)	Global initiatives, partnerships and investments in pharmaceutical manufacturing are valuable. However, to maximize the benefits of these initiatives, manufacturers should have a comprehensive understanding of the available resources and opportunities. By gaining insights into products with specific supported projects, funding mechanisms, and regulatory frameworks, manufacturers can strategically leverage these resources to accelerate their own efforts and contribute to the growth of regional pharmaceutical production.

1.3 Purpose

To develop a priority medical products list and a roadmap for regional manufacturing in Africa as a means to the self-reliance of the African pharmaceutical industry.

1.4 Objectives

1. To provide a strategic guide to pharmaceutical manufacturing stakeholders on areas that require focused investments to spur the development of the sector.
2. To guide policymakers at continental, RECs and national levels on priority medical products to provide incentives to in order to achieve greater health and economic impact.
3. To provide policymakers and pharmaceutical manufacturers with insights into products with specific supported projects to strategically leverage these resources to accelerate their own efforts and contribute to the growth of regional pharmaceutical production.
4. To maximize the benefits of supportive global health initiatives, take advantage of current available opportunities, identify synergies and remove any duplication of efforts in pharmaceutical manufacturing on the continent.

1.5 What the priority medical products list is not.

The priority medical products list is aimed to be a rolling list reviewed periodically (every five years), changeable routinely and informed by contextual changes in environment. The priority medical products list is not intended to:

1. Restrict or cause bias over medical products that have not been selected.
2. Cause bias over imports.
3. Change current national treatment regimens.

2 METHODOLOGY

2.1 Design

The exercise was conducted using both quantitative and qualitative methods. The quantitative methods included a secondary analysis of global disease burden data and qualitative methods involved a literature review of relevant documents, mapping of medical products prioritised by global and regional health initiatives and consultations with stakeholders. The development of a consolidated roadmap for regional pharmaceutical manufacturing in Africa was based on PMPA objectives and guided by a group of experts.

2.2 Inception

An inception report detailing the methods, criteria for prioritisation of medical products, mapping tool, relevant documents and reports for desk review, and work plan with timelines and deliverables of the assignment. A kick-off meeting was held with AUDA-NEPAD to discuss project expectations, timelines, and communication protocols, and to clarify the responsibilities of the stakeholders involved.
A stakeholder meeting was held on 26th July 2024 to agree on the methodology and the prioritization criteria for medical products, incorporating their feedback and insights to refine the criteria and ensure it addressed stakeholder considerations. The meeting was attended by a diverse range of participants representing organisations including representatives of RECs, UN agencies, civil society and representatives of the Federation of African Pharmaceutical Manufacturers' Association (FAPMA).

2.3 Data collection

Data collection was conducted in three stages to identify medical products ideal for local manufacturing in Africa. These are explained below:

Step 1: Identification of critical health needs for Africa

To understand Africa's critical health needs and the current landscape of local manufacturing efforts, we identified the top 10 disease burdens or conditions contributing to Disability-Adjusted Life Years (DALYs) in each country in Africa. Data was obtained from the WHO Global Health Observatory for all 54 African Countries . A comparative analysis of 2019 and 2020 data revealed minimal fluctuations, justifying the focus on 2021. For analysis, data was organized into Excel spreadsheets for each of the eight African Union Regional Economic Communities, enabling the identification of the top ten diseases within each economic region. Subsequently, a continental top ten list was compiled by aggregating regional data. Data on COVID-19 was excluded due to its pandemic status.

By cross-referencing the identified top ten diseases with the WHO Model List of Essential Medicines and individual country Essential Medicines Lists (EMLs), we determined the most critical drug treatments, accompanying diagnostics and vaccines. This analysis served as the foundation for prioritizing medical products needed in Africa.

Below are the steps in the identification of the priority medical products:

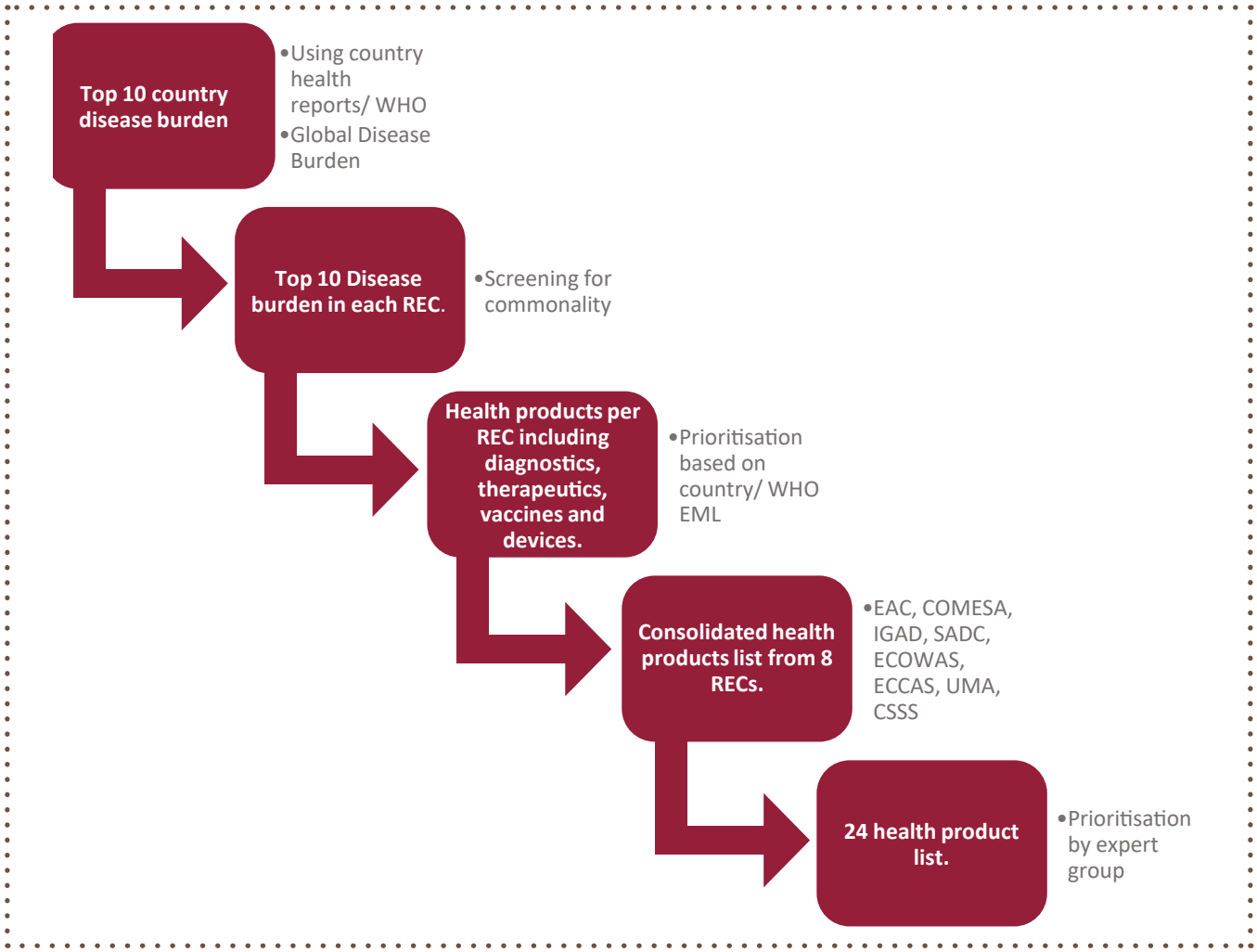


Figure 3: Medical products prioritisation process

Step 2: Categorisation of identified medical products

We adapted the Boston's Consulting Group (BCG) Model which is a business growth share matrix to develop an options analysis on investment decisions for the priority medical products. We plotted the burden of disease against possible market growth for investment in medical products for the diseases. The BCG Model has some limitations as it employs two dimensions of relative market share, and market. growth rate. These two factors cannot exclusively indicate the success, profitability or attractiveness of a product as there are many other business ecosystem factors. We mitigated these limitations of the Model by making consideration of some known enablers for the pharmaceutical manufacturing value chain. The details of the adapted BCG model are shown in figure 4 below.

Step 3: Identifying global and regional health policies and initiatives with priority medical products

We then reviewed existing prioritization policies and initiatives at country regional and global levels for promoting local manufacturing of specific essential medicines. These initiatives either emphasize the urgency or make a case for regional manufacturing of specific medicines, diagnostics and therapeutics.

Based on various considerations/ enablers shown in figure 4, we made recommendations for possible priority medical products to inform stakeholder discussions.

2.4 Stakeholder Engagement

We organized virtual and physical meetings with representatives from RECs, development partners, Ministries of Health and Trade, pharmaceutical manufacturers' associations including Federation of African Pharmaceutical Manufacturers Associations (FAPMA), Federation of East African Pharmaceutical Manufacturers (FEAPM), Southern African Generic Medicines Association (SAGMA), West African Pharmaceutical Manufacturers Association (WAPMA) and selected country private manufacturer associations, regulatory agencies, and public health and policy experts. During these meetings, we facilitated open discussions to select a list of 24 priority medical products for local production on the continent. Some of the considerations for the priority list included: whether the medical products had the greatest potential for public health impact, if there was available capacity for their manufacture, if there were intellectual property barriers (patents in place), availability of technology transfer, production inputs such as APIs, political support, pooled market, support from global health initiatives, economic viability of the product and equity considerations in available manufacturers. Experts rated the manufacture of each proposed health product according to the above enabling considerations and the results were presented as traffic light. *Annex II has the full list*.

A traffic light methodology represents the status of project activities. The method utilizes the three main colours of the traffic light – Green, Yellow, and Red – to indicate progress or current status of activities. In this assessment, we utilize three colours to show the extent to which particular considerations enable the manufacturing of selected health molecules. Color Definitions: Green: High Enabler; Yellow: Moderate Enabler; Red: Low Enabler for pharmaceutical manufacturing.

2.5 Development of regional value chain roadmaps

The roadmaps for regional manufacturing were based on the objectives and pillars of PMPA. The roadmaps are aimed to serve as a guide, outlining the key stakeholders, capacity-building needs, and collaborative strategies required to translate prioritized medical products into tangible realities in pharmaceutical production. In meetings with stakeholders, we discussed which PMPA pillars/ objectives would be most suitable, identified strengths and weaknesses in the RECs and possible interventions to

address identified priorities.

2.6 Development of a continental roadmap

An experts' consultative meeting was held in August 2024 in Dakar Senegal to review and validate the prioritised medical products list, and agree on objectives and interventions for a continental roadmap. Several other review and buy-in meetings were then held to bring together experts at RECs level in September 2024 in Kigali Rwanda, in November 2024 in Abidjan Ivory Coast and in December 2024 in Dakar Senegal. The continental roadmap presents a precise and actionable plan for strengthening local manufacturing capacity in Africa.

2.7 Finalization and dissemination of the report

The final report of the final continental priority medical products list and roadmap to self-reliance will be disseminated by AUDA-NEPAD to relevant stakeholders to ensure political buy-in and implementation of recommendations.

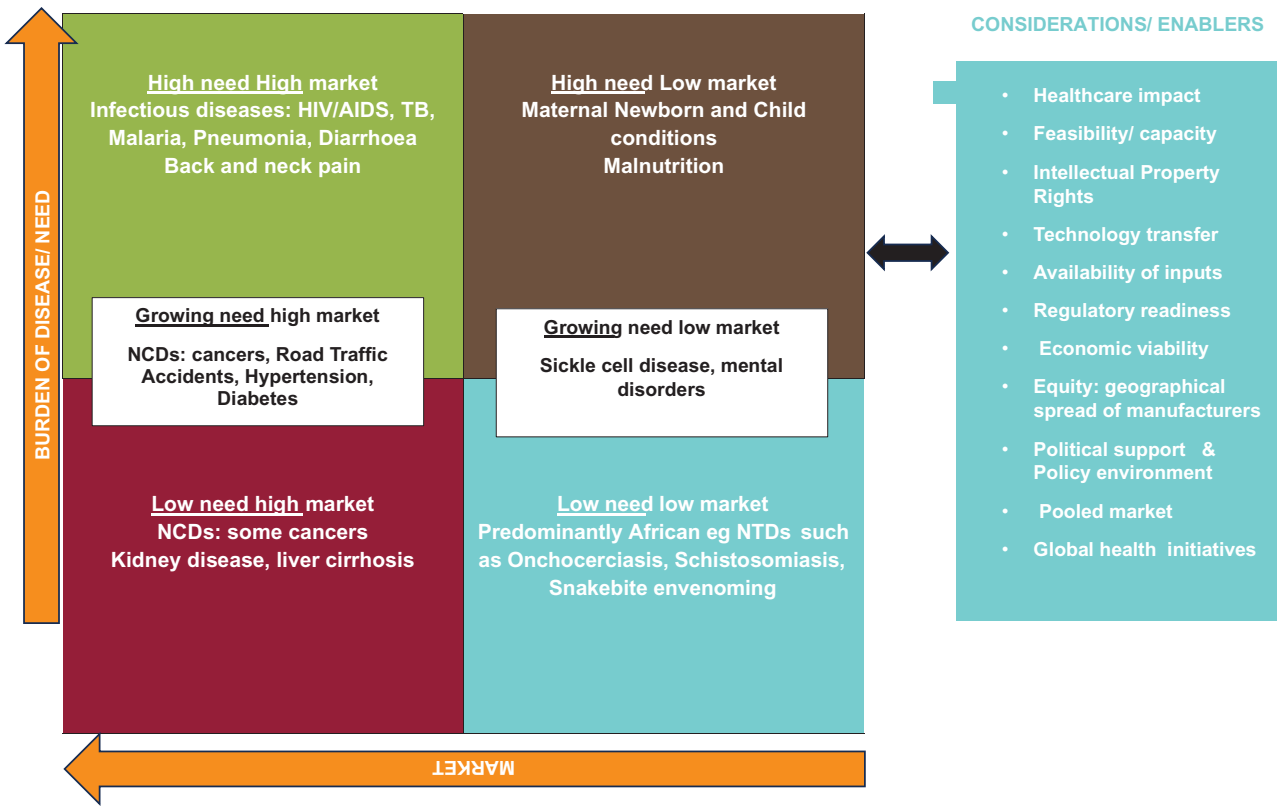


Figure 4: Options analysis matrix for prioritising health products

3 RESULTS
3.1 Top disease burden in Africa

Disease burden was used to calculate health needs for Africa. The top 10 diseases that contribute to DALYs across countries, RECs and the continent were analysed. The results are consistent across multiple years and there are similarities across countries as shown in the tables below. The disease burden in RECs is shown in the *Annex 1*.

Table 1: Top 10 Disease Burdens in Africa

No	Disease Burden	Total DALYs per 100,000 Population
1	Lower respiratory infections	191699.92
2	Preterm birth complications	158321.64
3	Malaria	150621.15
4	HIV/AIDS	142139.53
5	Diarrheal diseases	122229.07
6	Tuberculosis	105409.57
7	Birth asphyxia and birth trauma	91527.6
8	Stroke	68995.38
9	Road injury	42679.37
10	Congenital anomalies	40757.69

Table 2: Top common diseases across African countries

No	Disease	No. countries
1	Preterm birth complications	51
2	Lower respiratory infections	50
3	Stroke	44
3	Birth asphyxia and birth trauma	44
3	Diarrhoeal diseases	44
4	Tuberculosis	35
5	Congenital anomalies	34
6	Malaria	33
7	HIV/AIDS	32
8	Road injury	30
9	Ischaemic heart disease	21
10	Diabetes mellitus	14

Based on the top diseases, medical products required for the diseases were identified as shown in the table below:

3.2 Top disease burden in Africa with recommended medical products

Based on WHO EML, priority medical products for the above diseases were identified as below:

No.	Disease	Health product
1.	Preterm birth complications	1. Resuscitation devices 2. Antenatal Corticosteroids
2.	Lower respiratory infections	1. Amoxicillin 2. Amoxicillin + clavulanic acid 3. Cefotaxime 4. Ceftriaxone
3.	Diarrheal diseases	1. Oral rehydration salts; zinc sulfate
4.	Birth asphyxia and birth trauma	1. Medical Oxygen 2. Oximeter
5.	Stroke	1. Acetylsalicylic acid + simvastatin + ramipril + atenolol + hydrochlorothiazide 2. Atorvastatin + perindopril + amlodipine
6.	Congenital anomalies	1. Iron + Folic acid ((antenatal care required for pregnant women) 2. Surgical options
7.	Malaria	1. mRDTs 2. Artemether + lumefantrine 3. Artesunate + sulfadoxine-pyrimethamine 4. Dihydroartemisinin + piperaquine 5. Quinine Inj. 6. Artesunate Inj.
8.	Tuberculosis	1. TB Test kits 2. Ethambutol + isoniazid + pyrazinamide + rifampicin 3. Moxifloxacin
9.	Road injury	1. Blood substitutes 2. Intravenous fluids 3. Pain management 4. Sundries
10.	HIV/AIDS	1. HIV Test kits 2. Dolutegravir + lamivudine + tenofovir 3. Efavirenz + emtricitabine + tenofovir 4. Efavirenz + lamivudine + tenofovir 5. Abacavir + lamivudine 6. Lopinavir + ritonavir

11.	Ischaemic heart disease a- Angina Pectoris b- Acute Ischaemic heart disease c- Chronic Ischaemic heart disease	1. Bisoprolol 2. Glyceryl trinitrate 3. Verapamil 4. Carvedilol 5. Metoprolol 6. Clopidogrel 7. Enoxaparin 8. Heparin sodium 9. Acetylsalicylic acid + atorvastatin + ramipril 10. Acetylsalicylic acid + simvastatin + ramipril + atenolol + hydrochlorothiazide
12.	Diabetes mellitus	1. Glucose meters + strips 2. Metformin
		3. Insulin analogues 4. Gliclazide

3.3 Enabling considerations

The sections above highlight public health needs showing the disease conditions with the highest burden and the medical products that are required for their management/ mitigation. However, various factors have to be considered in making the final selection of priority medical products. These are highlighted below:

3.3.1 Global Health Initiatives

A number of global health initiatives have selected priority medical products for pharmaceutical manufacturing in Africa. A lot of research has gone into their recommendations. Alignment with these initiatives provides an opportunity for synergies and support and helps avoid duplication of efforts.

Below we describe priority medical products selected by some global health initiatives:

Coalition for Epidemic Preparedness Innovations

The Coalition for Epidemic Preparedness Innovations (CEPI) aims to "accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats" so that they can be widely accessible to populations in need in a short amount of time.

It currently focuses on vaccines against Lassa, MERS, Rift Valley Fever, Nipah, Chikunguya, Ebola, Covid-19, coronaviruses and Disease X, an unknown pathogen. CEPI takes an end-to-end approach and acts in two capacities, both as a funder and a facilitator, focusing on vaccine development, licensure and manufacturing, while supporting vaccine discovery, delivery and stockpiling, in partnership with industry, governments, academia, foundations, international organisations, civil society and regulators[130].

To realise this goal, CEPI engages in advocacy to make the broader health system more equitable; coordinates with partners to align investments and technologies; includes equitable access obligations in its investment agreements; and works only with partners that share its vision and mission.[131] In addition, when CEPI-funded vaccines are developed, it coordinates with relevant partners to enable them to be licensed or achieve appropriate regulatory milestones. When vaccines are licensed, it is committed to enable them to be procured, allocated, deployed and administered, at a price that is affordable for buyers and sustainable for manufacturers. [132]

To support vaccine R&D and manufacturing in Africa, since 2021 CEPI has launched different activities. In 2021, it signed a Memorandum of Understanding with the AU/Africa CDC to strengthen pandemic preparedness, "invest in vaccine R&D innovations", "invest in capacity building and training", support laboratories and research hubs, and "build partnerships that enable the sustainable expansion of vaccine manufacturing in Africa", while more broadly supporting and working with PAVM.[133] CEPI has funded clinical trials for vaccines against diseases that affect African populations (Ebola, Lassa Fever, MERS, COVID-19) in more than 15 countries in Africa, and is going to support clinical trial sites for a first-ever Phase 3 Lassa Fever vaccine efficacy trial in West Africa and to develop a strategy to enable long-

term epidemic research preparedness in the region. Moreover, it co-financed establishing alum vaccine fill/finish capability at Aspen (South Africa) broadening their scope and supporting an agreement with India's Serum Institute that allows technology transfer of four routine vaccines, in view of building Aspen's manufacturing and distribution capacity. [134]

The Institut Pasteur de Dakar joined the CEPI vaccine manufacturing network in January 2023, when it signed a 3-year, USD 15 million partnership with CEPI to establish bioprocess capability, expand production capacity for routine vaccines and reserve capacity for disease outbreaks. This involves strengthening DS manufacturing capacity, establishing a bioprocessing laboratory, investing in specialist skills development and supporting the Institute's quality management system.

Unitaid

Unitaid supports innovative solutions to address LMICs' major diseases – HIV, malaria, tuberculosis, HIV co-infections, cervical cancer, hepatitis C and fever management. In particular, it is committed to funding innovative health solutions and bringing them to the market, in collaboration with partners such as the Global Fund. Through short-term grants, it supports partners that can scale up these innovations so that they can be marketed more quickly and at a lower cost, hence making them more accessible to those in need[136]. To do so, it relies on a partnership approach that encompasses technical partners developing new solutions; private sector companies using their market power to lower the cost of innovations; funders lowering the cost of medicines and diagnostics through co-payments; implementing partners bringing innovations to the most affected communities; and civil society organisations raising awareness. [137]

Unitaid is focusing on Africa, where countries rely the most on imported medical products and where increased local capacity would greatly improve sustainability and access to products addressing regional needs. The goal is to transition to a sustainable African manufacturing industry that delivers a range of medical products at scale, meeting the required quality standards and priced competitively.
The prioritization by Unitaid was based on five key criteria: resilient and equitable public health opportunity; the transformative potential of technology platform(s); Unitaid's historical investment and level of effort; synergy with Unitaid's unique positioning; and product ecosystem and market readiness.

Based on this analysis, Unitaid identified five priority products from therapeutics, diagnostics and medical devices groups:

1) *New malaria treatments, including non-artemisinin-based drugs.*
2) *HIV treatments, including HIV medicines for children.*
3) *Better medicines for prevention and treatment of postpartum haemorrhage.*
4) *Rapid diagnostics tests for HIV and hepatitis C.*
5) *Next-generation long-lasting insecticide-treated nets for malaria.*

For each of these products, Unitaid has researched the feasibility, cost-effectiveness, and potential partners required to strengthen regional manufacturing capabilities in Africa. The research acknowledges that there are still gaps and barriers to be addressed, but these are surmountable. Very few countries are able to meet the minimum quantity for orders at reduced bulk prices. In their role as a connector, Unitaid is working to bring together the partners needed to help countries move toward supporting regional economic zones to pool demand.

Unitaid is also connecting with existing manufacturers in other regions that could provide technology transfer – training, equipment, and quality control guidance – to local producers to boost their capacity and meet required regulations. For example, to strengthen diagnostics manufacturing during the COVID-19 pandemic, together with FIND they spearheaded the transfer of rapid diagnostic testing technology across three continents, In Senegal, they partnered with FIND to support diaTROPIX, a nonprofit manufacturer that is part of Institut Pasteur Dakar. Bionote and Mologic, two diagnostics developers, provided technology transfer – the instructions, raw materials, equipment and quality control needed to create the tests – to diaTROPIX, enabling the production of high-quality tests in Senegal.

The antimalarial manufacturing value chain is already being nurtured in Africa, with significant historical investments delivering impact. There are several manufacturers of ACTs and other malaria medicines in Africa, notably in Nigeria, Kenya, Ghana, and Uganda. While many of these are of unknown quality status, efforts of governments and multiple stakeholders to collaborate with these manufacturers have yielded some positive results, including the following:

- Universal Corporation Limited (UCL) Kenya is the first African manufacturer to gain WHO prequalification for sulphadoxine/pyrimethamine (SP) to prevent malaria in pregnant women with support from Malaria Medicines Ventures (MMV) and Unitaid. In October 2023, UCL received WHO prequalification for SP+ AQ the combination treatment for seasonal malaria chemoprevention to protect children under 5.

- Cipla Quality Chemical Industries Ltd (QCIL) Uganda is listed as a manufacturing site for Cipla's WHO-prequalified artemether/ lumefantrine (AL) 20/120mg finished pharmaceutical product.

- Swiss Pharma Nigeria Limited (Swipha) and Emzor Pharmaceutical Industries Limited in Nigeria, with support from MMV and Unitaid, are developing a quality-assured, child-friendly, dispersible formulation of SP to protect women, children and infants from malaria. Swipha is expected to receive WHO prequalification for this product soon.

In November 2023 at the World Local Production Forum, Unitaid together with global and regional partners launched one of the first new initiatives under its regional

manufacturing strategy: the medical products Manufacturing Support Platform (HMSP). The HMSP aims to address the challenge of technical capacity for regional manufacturers in Africa. It will do so by matching opportunities for technical assistance related to technology, management, and operational skills, specific projects and skill sets, linkages to capital, and regulatory compliance.

On 19th June 2024, Unitaid posted a Call for Proposals (CFP) seeking to solicit proposals from organizations or consortia, including technical support organizations, non-government organizations (NGOs), market-shaping organizations, academic and research institutions with demonstrated competencies in upstream product development and manufacturing, and downstream activities, including in-country product access. This CFP aims to identify partners (or a consortium of partners) that can design and implement technical and market-shaping interventions to support manufacturers in achieving sustainable manufacturing and market entry of cost-competitive, quality-assured products within Unitaid's identified five priority products from therapeutics, diagnostics and medical devices groups.

This CFP aligns with recent calls to action, such as the "Declaration for accelerated malaria mortality reduction in Africa" and the "Lusaka Agenda: Conclusions of the Future of Global Health Initiatives Process that have been unequivocal on the need for urgent action for a speedy and coordinated approach to accelerating regional manufacturing as an enabler to equitable access.
On 8th July 2024, UNITAID posted a Call for Expressions of Interest (EOI) is to identify potential manufacturers that can contribute to enhancing supply resilience and access to medicines for treatment and/or prevention of postpartum haemorrhage, new malaria treatments and therapeutics for HIV and related co-infections, in Africa by strengthening regional manufacturing and developing the broader supply ecosystem. Unitaid intends to provide technical and financial support through implementing and collaborating the partners to enable selected Africa-based manufacturers and Contract Research Organizations (CROs) to improve the costs and quality of target products within the Unitaid portfolio.

GAVI

Gavi, the Vaccine Alliance, is a public-private partnership that helps vaccinate more than half the world's children against some of the world's deadliest diseases. Since its inception in 2000, Gavi has helped bridge the global vaccine equity gap by immunising over 1 billion children and halving child mortality in 78 lower-income countries.

In the wake of the COVID-19 pandemic, Gavi's 5.0 strategy (2021-2025) was revised to take into account the lessons learnt to be better prepared for future public health crises. This new evolution, articulated as "Gavi 5.1", therefore takes stock of the several local manufacturing initiatives that were introduced on the African continent, as well as the limited number of global suppliers for critical vaccines, such as rota (3 Gavi suppliers), measles-rubella (2), measles (2), cholera (2) and malaria (1)[138]. This has led to broad support for the expansion of African vaccine manufacturing capacity, with a new strategy approved by the Gavi Board in

December 2022. It shares CEPI's perspective regarding the importance of a strong foundation of routine vaccine production capacity, as a prerequisite for surge capacity for the next pandemic.

Given its two decades of experience in shaping sustainable, healthy market dynamics for vaccines which are accessible and affordable for lower-income countries, in 2021 Gavi started exploring how best to support the AU vision of sustainably expanding vaccine manufacturing capacity across Africa by 2040, in alignment with its mission and mandate[139]. This resulted in a new regional manufacturing strategy launched in 2022, developed by Gavi in response to the call to action from the African Union and the G7 Development Ministers under the German Presidency.

The African Vaccine Manufacturing Accelerator (AVMA) is a financing mechanism established to make up to US$ 1.2 billion available over ten years commencing with AVMA's launch in June 2024 to accelerate the expansion of commercially viable vaccine manufacturing in Africa. The instrument was approved by the Gavi Board in December 2023 and launched in June 2024, following a design process conducted over nearly two years of close collaboration between Gavi, the African Union and the Africa Centres for Disease Control and Prevention (Africa CDC), with extensive consultations with partners, donors, industry, civil society and other stakeholders. Due to the high startup costs for vaccine manufacturing, the commercial sustainability required for ongoing supply security is unlikely to develop without downstream incentives. AVMA aims to contribute to two overarching objectives:

a) a sustainable African manufacturing base that contributes to healthy global vaccine markets; and
b) improved pandemic and outbreak vaccine supply resilience in Africa.

Vaccine Innovation Prioritisation Strategy

The Vaccine Innovation Prioritisation Strategy (VIPS) represents an unprecedented three-year collaboration – known as the VIPS Alliance – between the Gavi Secretariat, World Health Organization (WHO), Bill & Melinda Gates Foundation, UNICEF and PATH. Its purpose is to develop a single integrated framework to evaluate, prioritise and drive forward vaccine product innovations[140].

UN life-saving commodities

In 2010, the UN Secretary-General's Global Strategy for Women's and Children's Health highlighted the worldwide suffering of women and children caused by lack of access to life-saving commodities. The Strategy called on the global community to work together to save 16 million lives by 2015 through increasing access to and appropriate use of essential medicines, medical devices and health supplies that effectively address leading avoidable causes of death during pregnancy, childbirth and childhood[141].

This challenge was taken up by the UN Commission on Life-Saving Commodities for Women and Children (the Commission), which is a part of the "Every Woman, Every Child" (EWEC) movement and has the overall goal to increase access to these life-saving commodities in 50 of the world's poorest countries. With a strong focus on the reproductive, maternal, newborn and child health (RMNCH) "Continuum of Care", the Commission identified and endorsed an initial list of 13 overlooked life-saving commodities.

The Commission also identified key, interrelated barriers that prevent access to and use of the 13 commodities. These include severely under-resourced regulatory agencies in low-income countries, leading to delayed registration of commodities; lack of oversight of product quality and general inefficiencies; market failures, where the return on investment is too low to encourage manufacturers to enter the market or produce sufficient quantities; and user supply and demand challenges such as limited demand for the product by end-users, local delivery problems and incorrect prescription and use.

To address these challenges and deliver on the promise of saving the lives of millions of women and children, the Commission recommended 10 time-bound actions. These focus on the need for improved global and local markets for life-saving commodities, innovative financing, quality strengthening, regulatory efficiency, improved national delivery of commodities and better integration of private sector and consumer needs.

The Lifesaving commodities are in table below:

Table 3: UN Commission Lifesaving commodities

Category	Health product
Maternal health	• Oxytocin; postpartum hemorrhage • Misoprostol; postpartum hemorrhage • Magnesium sulphate; pre-eclampsia and eclampsia
New born health	• Injectable antibiotics: newborn sepsis • Antenatal corticosteroids: pre term respiratory distress syndrome • Chlorhexidine: new born cord care • Resuscitation devices: new born asphyxia
Child health	• Amoxicillin for pneumonia • Oral rehydration salts for diarrhea • Zinc for diarrhea
Reproductive health	• Female condoms • Contraceptive Implants • Emergency contraception

Partnership for African Vaccine Manufacturing

Africa CDC's Partnership for African Vaccine Manufacturing (PAVM) developed a Continental Strategy for an integrated ecosystem to generate investments in all steps of the vaccine manufacturing supply chain to develop and produce Africa-specific vaccines independently, with greater capacity .

An assessment conducted which led to 22 prioritized diseases as below:

- Ten legacy diseases, which typically have high volumes of vaccines available are , primarily produced by Indian players with low unit prices. These vaccines can offer economies of scale if produced on the continent.

- Six expanding diseases, which typically do not yet have commoditized vaccines, or have vaccines with relatively higher prices, with some products still in development that are not yet licensed. A number of diseases endemic to Africa (for instance, HIV) are included, and the development of vaccines against these diseases is of high importance for the continent.

- Six outbreak diseases, which typically have vaccines with unpredictable demand driven by outbreaks, often with higher prices due to lower scale and urgent need. These diseases are prioritized to quickly meet the required need for vaccines in times of outbreaks.

The vaccines prioritized are below:

Table 4: PAVM priority list of vaccines for 22 diseases

Archetype	Diseases
Legacy diseases	Hepatitis B Diphtheria Tetanus Whooping Cough Tuberculosis Measles Yellow Fewer Cholera Typhoid Meningococcus
Expanding diseases	Human Papillomavirus Pneumococcus Rotavirus COVID-19 Malaria HIV
Outbreak diseases	Ebola Influenza Chikungunya Rift Valley Fever Lassa Fever Disease X.

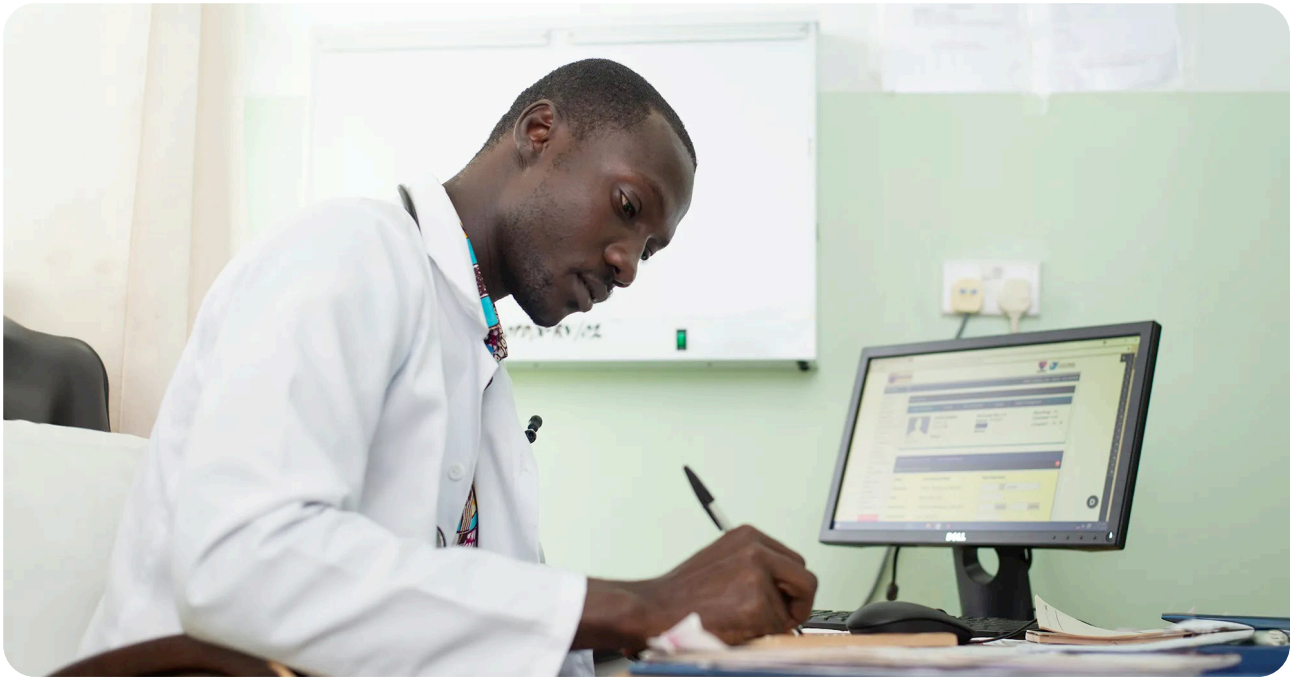
WHO, THE GLOBAL FUND, PEPFAR

The Global Fund to Fight AIDS, Tuberculosis and Malaria (the "Global Fund"), PEPFAR and Unitaid support the procurement of large amounts of diagnostic products and related laboratory items for the diagnosis and management of HIV/AIDS. In December 2010, the Global Fund established the Global Fund Quality Assurance Policy for Diagnostic Products ("the QA Policy"). The QA Policy applies to, among other products, HIV, TB and malaria Rapid Diagnostic Tests (RDTs). In May 2017, the Global Fund revised its QA Policy1 to align with the changes to the WHO criteria used to determine procurement eligibility for malaria RDTs.[132]

Currently, the Global Fund and PEPFAR do not procure any professional use HIV RDTs from manufacturers in Africa. However, PEPFAR aims to procure 15 million HIV tests produced by African manufacturers in 2025 at an estimated cost of $20 million. To support the development of quality assured African

manufacturing of diagnostics and facilitate uninterrupted supply of RDTs for HIV for use in Africa, according to the requirements of the revised QA Policy, the Global Fund, PEPFAR and Unitaid are launching a pilot Expert Review Panel for Diagnostic Products (ERPD) review for HIV RDTs for professional use and self-testing manufactured in Africa. Manufacturing in Africa is defined as operations happening indigenously in one of the 55 member states of the African Union.

The Global Fund is inviting manufacturers of HIV in-vitro diagnostic products conducting some, or all, of the manufacturing steps in Africa to submit their product information for review. Once a submission is accepted by the Global Fund, the ERPD – an independent panel of technical experts convened by WHO – will conduct an assessment of the potential risks linked to the procurement and use of such diagnostic products that have not yet been prequalified by WHO or authorized for use through a stringent regulatory review. This ERPD pilot is intended to support the expansion of quality-assured RDT manufacturing in Africa. To fully realize this objective, manufacturers should work towards incorporating all production steps - from assembly and kitting to subcomponent and reagent manufacturing, to enable end-to-end production of finished products in Africa within the next ten years.



3.4 Support from multinational companies

Support from multinational companies can support capacity building, the technology transfer and help circumvent intellectual property rights barriers. The Access to Medicines Index has highlighted support from multinational pharmaceutical companies to local pharmaceutical manufacturing industry in Africa. The partnerships with the local companies and governments are aimed at creating sustainable manufacturing ecosystems; sharing technical expertise and knowledge to build local capacity and enable the production of complex products; and establishing or expanding manufacturing facilities in African countries to produce a variety of essential medicines while adhering to local regulations and standards to ensure product quality and safety. The efforts are aimed at enhancing access to medicines, developing local capabilities, and contributing to economic growth. Below are the different initiatives:

- Merck KGaA: Merck a leading science and technology company, in collaboration with the Paediatric Praziquantel Consortium led by Consortium partner Farmanguinhos entered into a contract manufacturing agreement with Universal Corporation Ltd Nairobi, Kenya in 2022 for the large-scale production of the new paediatric medication. Production will begin once the medication has been registered. The drug is needed to treat the neglected tropical disease (NTD) schistosomiasis in preschool-aged children younger than six and is currently in late-stage development (currently in clinical Phase III). The agreement with Universal includes building up extensive production

capacities in Nairobi, Kenya for future provision of the treatment in endemic African countries.

- Sun Pharma and Cipla of India: have a strong presence in African markets, with manufacturing facilities producing a range of essential medicines, including antiretrovirals, antibiotics, and antihypertensives in Kenya, Nigeria, and South Africa.

- Viatris: Partners with local companies in Mozambique and Kenya for packaging and distributing ARVs, emphasizing the development of local capacity.

- Johnson & Johnson: In 2022 announced plans to manufacture its COVID-19 vaccine in South Africa through a partnership with Aspen SA Operations.

- Pfizer: In 2022 transferred technology for pneumococcal and COVID-19 vaccines to manufacturers in Brazil and South Africa, aiming to increase vaccine availability in the region.

- Sanofi: Nigeria had since 1995 adopted a policy to manufacture at least 70% of its essential medicines locally. In 2019, the National Agency for Food and Drug Administration and Control in Nigeria introduced the Five Plus Five-Year Validity (Migration to Local Production) policy,2 in support of producing essential medicines locally. In line with this policy, as of 1 May 2019, a newly registered imported product is given a maximum period of 10 years (five years of initial registration plus another five years of renewal registration) to migrate to local production. As a direct response to the new policy, Sanofi Nigeria Limited, a subsidiary of the French pharmaceutical giant Sanofi. Signed an agreement with May & Baker Nigeria Plc. to produce antibiotics, complying with local regulations and transferring essential manufacturing knowledge. The products which May & Baker would manufacture for Sanofi include Flagyl tablets and Suspension and Tarivid tablets, anti-infective medicines and Malareich tablets an anti-malaria.

The Access to Medicines Foundation

The Access to Medicines Foundation has conducted an analysis to identify diseases with significant health impact where local production of essential treatments ought to be prioritized as below:

1) *Maternal Health: Focus on postpartum haemorrhage and access to oxytocin.*
2) *Non-Communicable Diseases (NCDs): Focus on diabetes and access to insulin.*
3) *Sickle Cell Disease: Focus on access to hydroxyurea.*
4) *Neglected Tropical Diseases (NTDs): Focus on specific diseases like human African trypanosomiasis, visceral leishmaniasis, and leprosy.*
5) *HIV, Malaria, and Tuberculosis:* Emphasis on local production efforts for critical treatments.

Examples of Company Support include:

- *Merck collaborating with partners to advance heat-stable carbetocin for postpartum haemorrhage.*
- *Sun Pharma has a co-marketing agreement for heat-stable carbetocin in India.*
- *Novartis has an Africa SCD program to increase access to hydroxyurea for sickle cell disease.*
- *Sanofi's fexinadozole for sleeping sickness is undergoing WHO prequalification for wider use.*
- *Gilead donates Amphotericin B liposome for visceral leishmaniasis treatment in six countries.*
- *Novartis donates a combination therapy for leprosy elimination in 83 countries.*
- *GSK's malaria vaccine Mosquirix is being manufactured locally through technology transfer.*
- *ViiV Healthcare has a voluntary licensing agreement for CAB-LA PrEP to increase access for HIV prevention.*
- *Johnson & Johnson granted licenses to enable generic production of bedaquiline for tuberculosis treatment.*

The above efforts indicate positive strides towards strengthening Africa's pharmaceutical industry. However, continued investment and collaboration between governments, companies, and local stakeholders are crucial for realizing the full potential of local manufacturing in Africa.

3.4.1 Ecosystem enablers for Local Pharmaceutical Manufacturing in Africa

Local pharmaceutical manufacturing in Africa holds immense potential for improving healthcare access and economic growth. Several key factors have been extensively researched and proposed to facilitate the development of the sector:

1. Feasibility/Capacity: Developing a skilled workforce is essential for the pharmaceutical industry[133]. This involves investing in education, training, and capacity building to address shortages in skilled labour. Additionally, ensuring that manufacturing facilities adhere to Good Manufacturing Practices (GMP) standards is crucial for producing high-quality medicines[134].

2. Technology Transfer and Innovation: Transferring technology and knowledge from developed countries to Africa is vital for the growth of the pharmaceutical sector[135]. Partnerships with international companies can accelerate this process. Moreover, fostering innovation and research and development (R&D) locally is essential for long-term sustainability[136].

3. Availability of inputs: Increasing local production of Active Pharmaceutical Ingredients (APIs) is crucial to reduce reliance on foreign suppliers and mitigate supply chain risks[137]. This will enhance the industry's resilience and foster innovation within the region[138].

4. R**egulatory readiness**: Harmonized, predictable, and robust regulatory frameworks are essential for attracting investment and ensuring the quality, safety, and efficacy of medicines[139]. Building the capacity of national regulatory authorities and aligning regulations across African countries will create a level playing field for local manufacturers.[140]

5. **Economic Viability and Market Access**: Creating a conducive economic environment with incentives, affordable financing, and market access is crucial for the growth of the pharmaceutical industry[141]. Establishing regional pharmaceutical manufacturing hubs can leverage economies of scale and enhance competitiveness.

Africa Development Bank has proposed 4 pharmaceutical hubs based on regional proximity and Regional Economic Communities to facilitate pharma trade integration[142]. In each hub, potential nerve centres were identified. These are countries with developed or potential pharma industry[143].

- *In West Africa, proposed countries include; Côte d'Ivoire, Ghana, Nigeria and Senegal.*
- *In Southern Africa, the proposed countries include; Mauritius, South Africa, and Zambia.*
- *In East Africa; Ethiopia, Kenya, Rwanda, Tanzania, and Uganda.*
- *And in North Africa the countries include: Egypt, Morocco, Algeria, and Tunisia.*

6. Equitable Development: Ensuring a geographically balanced distribution of pharmaceutical manufacturing facilities is important for equitable access to medicines and promoting local economic development in the different regions[144].

7. Government Support and Policy: Strong political commitment and supportive policies are indispensable for the success of the pharmaceutical sector[145]. Governments should create an enabling environment through incentives, investments in R&D, and public-private partnerships.

8. Intellectual Property Rights: Optimizing intellectual property rights (IPRs) is essential for balancing innovation and access to medicines. African countries should leverage TRIPS flexibilities to promote local manufacturing while protecting public health interests[146].

9. International Collaboration: Leveraging global health initiatives and partnerships can provide valuable support for capacity building, technology transfer, and market access.

Collaboration with international organizations can accelerate the development of the pharmaceutical sector in Africa[147].

The ongoing initiatives by global institutions and African governments to promote regional pharmaceutical manufacturing represents a significant opportunity to strengthen value chains for critical medical products. By building upon these existing investments, it is possible to create a more sustainable and affordable supply of essential medicines for people in low- and middle-income countries.

3.4.2 Options analysis for priority medical products

The adapted BCG Model matrix provides six options/ categories of medical products for consideration. These are highlighted below and in table 5:

1) High need, High market

The medical products used to manage infectious diseases like HIV, tuberculosis (TB), malaria, pneumonia and diarrhea are in high demand from governments because these diseases form the highest burden in Africa. Since these diseases present the highest disease burden on the continent, there is a significant market for these medical products. Accordingly, this high demand presents a substantial opportunity for local production of these medical products, which can help meet the needs of the population and potentially boost the local economy. There are already several manufacturers on the African continent that produce these medical products. For instance, there are manufacturers of ARVs in Egypt, Ghana, Kenya, Mozambique, Nigeria, South Africa, Uganda and Zimbabwe. Hence, for high-burden medical products, there is some manufacturing capacity on the continent. What is needed is to create a viable market and build capacity for expended local production.

2) Growing need, high market

Despite the burden of infectious diseases being high, Africa is experiencing a growing burden of non-communicable diseases, such as cancers, road traffic accidents, hypertension, and diabetes. This is attributed to high population growth rates and sedentary lifestyles. There are local producers of some of the medical products for these conditions across the different RECs – mostly focusing on older molecules. In Africa, Egypt and South Africa are the two countries currently manufacturing oncology drugs, leaving a gap in sub-Saharan Africa. In South Africa, Fine Chemicals, an Aspen subsidiary, produces the API for Vincristine, a drug with a wide spectrum of uses in oncology.[148] and Adcock Ingram[149] produces a couple of anticancer drugs. Eva pharma in Egypt also produces anti-caners[150,151].

For other conditions: Aspen Pharmacare in South Africa produces general anaesthetics, pain management medications, antihypertensives and antidiabetic medical products; and Universal Corporation in Kenya produces antihypertensive medications. There is needs for collaboration to enhance capacities through technologies with multinationals and investment in R&D.

3) High need, Low market

Here we have placed mostly maternal and neonatal conditions, the medical products for which are delivered with support from development partners such as through social marketing. Examples are family planning commodities which if are not subsidized, the population and governments may not be able/ willing to afford them. Most of the medical products in this category such as contraceptive implants and condoms, are not produced in Africa.

Snapshot of MHP manufactured in Africa

Magnesium sulphate	4 producers in Ethiopia, Kenya, Nigeria, South Africa
Oxytocin	1 producer in Nigeria
Misoprostol	1 Producer in Nigeria
Tranexamic acid	1 producer in Kenya
Heat stable carbetocin	0 producer

Source: Reproductive Health Supplies Coalition[152].

The limited production of these highly needed medical products provides a case for investment by the private sector but will require public investment in human resources and infrastructure.

4) Growing need, Low market

These consist of disease conditions which are predominantly of African nature, such as Sickle cell disease, and mental health disorders. These conditions may be associated with myths and social stigma. Medicines used in the management of these conditions are old molecules.
Africa is also experiencing public health emergencies with sporadic outbreaks of Ebola, Marburg and cholera, and Mpox. Vaccines and therapeutics for these conditions are dependent on external manufacturers and funding support.

Investments are required in human resources and infrastructure development –with little return on investment, if any. This may not be attractive to the private sector and will require government and development partner investment.

5) Low need, High market

In this category, we have low-burden disease conditions, such as kidney disease and liver cirrhosis but the medical products are high value and some high-income patients are willing to pay. These include medical products used in cancer chemotherapy, kidney dialysis, and hepatitis treatment. The medical products require high investments in R&D and super-specialized ecosystems for their administration. They may, therefore be capital intensive. Partnerships and collaboration throughout the manufacturing value chain may be required.

6) Low need, Low market

This category includes medical products for neglected tropical diseases (NTDs), such as onchocerciasis, schistosomiasis, and snakebite envenoming, which affect mostly low-income communities. On a continental/ regional scale, the burden of these health conditions is not high, and so is the value of the market. They are typically supported through donor programs.

Production of these medical products by the private sector may not be viable without government or donor support.

Table 5: Priority medicines for Pharmaceutical Manufacturing in Africa.

High need High market A. Antibiotics: - Amoxicillin B. HIV/AIDS: - Cabotegravir - HIV Tests, - ARVs: Tenofovir +Lamivudine+ Dolutegravir. C. Pain management: - Paracetamol D. Antimalarials: - Artemether + Lumefantrine, Sulfadoxine pyrimethamine, RDTs E. Tuberculosis: - Bedaquiline	**High need Low market** A. Maternal health: - Oxytocin - Misoprostol - Magnesium sulphate B. Newborn: Birth asphyxia and birth trauma - Medical Oxygen **C.** Child health: Antidiarrheals: - Rotavirus Vaccines - ORS and Zinc
Growing need high market A. Stroke: - Atorvastatin - Valsartan. B. Injuries: - Intravenous fluids C. Diabetes: - Metformin - Insulin analogues. D. IHD/ Hypertension: - Amlodipine	**Growing need low market** A. Sickle cell disease: - Hydroxyurea
Low need high market A. Cancer: - Docetaxel	**Low need low market** A. NTDs: - Praziquantel

3.5 Justification of Priority Medical Products

High need High Market

A. Antibiotics:
Amoxicillin

Approximately 172 deaths per 1,000 live births occur in sub-Saharan African countries, with pneumonia being the major cause. Clinical evidence supports amoxicillin, particularly in its broad-spectrum antibiotic form, as effective for treating children with pneumonia. Among various forms of amoxicillin (syrup, dry powder for suspension, dispersible tablets), dispersible tablets (DT) are the most convenient for administration, shipping, and storage. The United Nations Children's Fund (UNICEF) advocates for amoxicillin DT, and the World Health Organization (WHO) included it in the Expression of Interest (EOI) list in 2015.

Despite global efforts, the adoption of amoxicillin DT for treating pneumonia in Africa has been slow. Four firms are amoxicillin DT manufacturers in Africa; two in Nigeria, one in Kenya, and one in Uganda. Two firms (Kenya and Tanzania) are at varying stages of generic formulation R&D. Manufacturers main challenges in the production of amoxicillin DT include difficulty in souring of quality APIs and its full characterization by the API manufacturers, on-shelf discoloration of the product, registration approvals take long due to compilation of common technical document (CTD) dossiers for regulatory purposes, lack of equipment for bioequivalence studies.

Key interventions to strengthen local production of amoxicillin DT should consider addressing challenges in bioequivalence by funding the purchase of analytical equipment as well as harmonizing bioequivalence data in the region; reviewing government tariffs on value-added taxes on APIs which increases cost of production and training on CTD dossier preparation and submission[153].

B . HIV/AIDS
Cabotegravir

Sub-Saharan Africa bears the brunt of the global HIV/AIDS epidemic, accounting for a staggering 75% of the disease burden. Effective HIV prevention and treatment are paramount to mitigating the impact of this crisis. Cabotegravir, a long-acting, injectable formulation, offers a significant advantage over oral medications. Its long-acting protection, requiring injections only every two months for PrEP (pre-exposure prophylaxis) and every month for treatment, dramatically improves adherence and reduces the risk of missed doses. This is particularly crucial for populations with limited access to healthcare and those facing potential stigma associated with daily medication.

While the current manufacturing capacity for cabotegravir in Africa is limited, there is strong support from global health initiatives like UNITAID and the PrEP GSK Viiv Healthcare/ViiV/MPP voluntary licensing agreement, which facilitates local production. With technology transfer already in place, there is needs to prioritize and advocate for local manufacturing of cabotegravir. This will not only ensure greater access to this vital medication but also strengthen healthcare systems and promote economic development within the region.

HIV Tests

Africa continues to grapple with the HIV/AIDS epidemic, making accurate and affordable HIV testing a critical component of early diagnosis, treatment, and prevention efforts. While the need for these tests is immense, current local manufacturing capacity remains limited.

However, there are promising signs. Revital, a company in Kenya, is already producing HIV/Malaria tests and syringes, demonstrating the potential for local production. Furthermore, the existence of a Good Manufacturing Practices (GMP) roadmap and regulatory frameworks provides a solid foundation for supporting and enabling local manufacturing. The Africa Medical Device Forum can play a crucial role in harmonizing regulations across the continent, further streamlining the process. Global health initiatives like PEPFAR are also seeking manufacturers for the Global fund.

Prioritizing local manufacturing of HIV tests will not only make quality tests more affordable but also contribute to increased testing rates in Africa and thus earlier diagnosis and linkage to care.

ARVs: Tenofovir + Lamivudine + Dolutegravir

The global HIV/AIDS epidemic disproportionately affects sub-Saharan Africa, where a staggering 75% of the disease burden resides. To effectively address this crisis, prioritizing HIV prevention and treatment strategies is paramount. The combination of tenofovir, lamivudine, and dolutegravir (TLD) is a crucial component of effective HIV treatment.

The feasibility of local TLD production is supported by a number of factors. Global health initiatives like UNITAID, PEPFAR, and the Global Fund provide substantial support for HIV prevention and treatment, including the development of local manufacturing capabilities. Technology transfer for TLD production is readily available, facilitating the establishment of local manufacturing facilities. The current regulatory landscape in sub-Saharan Africa is capable of overseeing the manufacture of ARVs like TLD, ensuring quality and safety standards are met. Local manufacturers have access to the market for TLD, enabling them to distribute the medication effectively. Furthermore, the policy environment is highly supportive of combating HIV, with numerous policies aimed at expanding access to treatment and care. While intellectual property rights may present a barrier, the possibility of negotiating compulsory licensing agreements provides a pathway to overcome this hurdle.

In conclusion, the combination of global health initiatives, technology transfer availability, a supportive regulatory landscape, market access, and a strong policy environment makes local TLD production in sub-Saharan Africa a highly viable and necessary endeavour.

C. Pain management
Paracetamol

Paracetamol, a widely used pain reliever and first-line fever reducer is essential for treating a myriad of conditions. Despite its widespread use, many African countries still rely heavily on imported paracetamol brands.

The simplicity of paracetamol production, coupled with the absence of intellectual property rights and readily available technology transfer, makes it an ideal candidate for local manufacturing. Manufacturers also have readily available market access.

Furthermore, advocating for local paracetamol production is relatively straightforward, as it resonates with both public health needs and economic development goals. It provides a compelling argument for a moratorium on imports to be presented to Heads of State. This investment would ensure and encourage the manufacture of other high-quality product lines.

D. Antimalarials
Sulfadoxine-pyrimethamine

The WHO African Region continues to carry a disproportionately high share of the global malaria burden. In 2022 the Region was home to about 94% of all global malaria cases (249 million cases) and 95% of deaths. Children under 5 years of age accounted for about 78% of all malaria deaths in the region. Four African countries accounted for just over half of all malaria deaths worldwide: Nigeria (26.8%), the Democratic Republic of the Congo (12.3%), Uganda (5.1%) and Mozambique (4.2%)[154].

Chemoprevention refers to the use of drugs to prevent malaria in special risk groups. WHO recommends several chemoprevention strategies for malaria control. Seasonal malaria chemoprevention (SMC) were recommended in 2012 and updated in 2022 to Intermittent preventive treatment of infants (IPTi) largely relying on sulfadoxine-pyrimethamine (SP) to prevent malaria in children in age groups at high risk of severe malaria in areas of seasonal malaria transmission by providing repeated treatment

with antimalarial drugs during peak transmission seasons[155]. In 2022, 250 mg Sulfadoxine-12.5 mg pyrimethamine dispersible tablets for use in infants (IPTi) was approved by Global Fund Expert Review Panel for use in infants & WHO recommends IPTi-SP for infants living in areas with moderate-to-high malaria transmission in sub-Saharan Africa. Treatment should be given three times during the first year of life at intervals corresponding to routine vaccination schedules. This intervention has been shown to reduce clinical malaria, anaemia and severe malaria in children under the age of one.

WHO also affirmed the effectiveness of Intermittent preventive treatment during pregnancy (IPTp) using SP (IPTp-SP), including in areas with SP resistance. The full course of IPTp-SP decreases the incidence of low birth weight babies by 29%, severe maternal anaemia by 38%, and neonatal mortality by 31% which are primary complications responsible for nearly 75 percent of these maternal & neonatal deaths within Sub-Saharan Africa[156]. Intermittent preventive treatment during pregnancy (IPTp) focuses on the delivery of 3 tablets of 500 mg sulfadoxine - 25 mg pyrimethamine (SP), to be given monthly at the beginning of the second trimester of pregnancy until delivery.[157]

WHO Prequalification in August 2022 approved Universal Corporation Limited in Kenya as the first African manufacturer of sulfadoxine-pyrimethamine in SSA region. UCL is now looking to achieve country registrations in Uganda, Rwanda, Zambia, Malawi and Tanzania.

Artemisinin-based combination therapies: Artemether + Lumefantrine

According to data from the World Health Organization (WHO), 608,000 people died from malaria worldwide in 2022 – 95% of those were in sub-Saharan Africa, and 78% of those were children under 5. But despite shouldering the largest global burden, Africa produces very few antimalarial treatments – the simple, cost-effective cure for the disease. Most artemisinin-based combination therapies (ACTs) are procured from China and India. Although malaria case incidence has reduced dramatically since 2000, progress has stalled and urgent threats like antimicrobial resistance and climate change are emerging. The main WHO recommended antimalarial treatment – artemisinin-based combination therapy – is losing its effectiveness as the malaria parasite develops resistance. Scientific modelling suggests that diversification of available treatments is one of the effective approaches to stay ahead of the resistance.

Recent calls to action, such as the "Declaration for accelerated malaria mortality reduction in Africa"1 and the "Lusaka Agenda: Conclusions of the Future of Global Health Initiatives process"[158] have been unequivocal on the need for urgent action for a speedy and coordinated approach to accelerating regional manufacturing as an enabler to equitable access

WHO recommends the use of six artemisinin-based combination therapies to treat most cases of malaria: artemether-lumefantrine (AL), artesunate-amodiaquine (ASAQ), artesunate-mefloquine (ASMQ), dihydroartemisinin-piperaquine (DHAP), artesunate sulfadoxine-pyrimethamine (AS+SP), and artesunate-pyronaridine (ASPY). Despite the existence of multiple recommended treatment options, the antimalarial market in Africa is dominated by a single ACT: artemether-lumefantrine (AL). This dominance is potentially driving resistance to artemisinin in Africa. Artemisinin partial resistance[159] has been confirmed for the first time in Africa, specifically in Eritrea, Tanzania, Rwanda and Uganda, and experts believe the problem is likely even more widespread. With Africa's heavy reliance on ACTs, the threat of drug resistance, including partner drug resistance on the continent, must be urgently addressed to avert the potential escalation to widespread clinical treatment failures. [160]

No single tool will stop malaria, which is why Unitaid and its partners are supporting a range of tools: new vector control products like insecticide-treated nets and spatial repellents to protect people indoors, the introduction of the world's first malaria vaccine

for children under 5, and preventative treatments for pregnant women and children. To fight drug resistance, Unitaid is also helping countries deploy strategies that diversify antimalarial treatment use, as modelling suggests that this is one of the approaches that can help mitigate and stay ahead of parasite resistance. Most of these treatments, however, are currently produced outside of Africa – mainly in the pharmaceutical powerhouses of China and India. Building regional manufacturing capacity to manufacture effective malaria medicines in Africa can help enable sustainable access to diversified treatments on the continent.

By strengthening regional manufacturing capacity to produce new antimalarials, including non-artemisinin based treatments, and helping to diversify the use of recommended treatments, we can help fight drug resistance and strengthen health security for millions of people at risk of malaria in Africa. Unitaid has identified opportunities for interventions that address these barriers to achieve scale, cost-effective, sustainable and commercially viable manufacturing of new antimalarials in Africa.

There are several key challenges that must be overcome, including the cost and complexity of achieving quality and regulatory compliance, poor access to finance, suboptimal infrastructure, and unpredictable public sector demand. Strengthening regional manufacturing will therefore take a coordinated effort across a range of partners, including regional manufacturers well-placed to expand; manufacturers able to provide technology transfer; national governments and regional blocs facilitating trade and creating regional markets; pooled procurement platforms; and partners that buy the products[161].

Universal Corporation Limited (UCL) Kenya is the first African manufacturer to gain WHO prequalification for SP to prevent malaria in pregnant women. Swiss Pharma Nigeria Limited (Swipha) and Emzor Pharmaceutical Industries Limited in Nigeria, with support from MMV and Unitaid, are developing a quality-assured, child-friendly, dispersible formulation of SP to protect women, children and infants from malaria. Swipha is expected to receive WHO prequalification for this product soon.

On APIs, manufacturing capacities are emerging on the continent, with Mangalam Drugs & Organics Ltd., a pharmaceutical and API manufacturer in India, having entered into a technology transfer agreement with Emzor to support the production of five antimalarials: artemether, dihydroartemisinin, lumefantrine, sulfadoxine, and pyrimethamine. The API

manufacturing facility is expected to start functioning in 2025 with a projected annual capacity of 400 metric tonnes.
The gap remains in investments in long-term insecticide treated mosquito nets and spatial repellants to protect people indoors.

E. Tuberculosis
Bedaquiline

Bedaquiline is a crucial medication for treating drug-resistant tuberculosis (DR-TB), a growing threat in Africa. Prioritizing local manufacturing of Bedaquiline is essential to combat this growing challenge.

Currently, there is a lack of local production capacity for Bedaquiline in Africa. However, there are existing global initiatives, such as Stop TB partners, that can be leveraged to enhance local production of this vital drug. Collaborating with these initiatives can facilitate technology transfer, capacity building, and regulatory support, paving the way for sustainable local manufacturing.

High need Low market

A. Maternal medical products (oxytocin, misoprostol, magnesium sulphate, heat stable Carbetocin)[162]

In 2020, WHO estimated that 287,000 women died due to preventable causes related to pregnancy and child birth. Nearly 70 percent of all maternal deaths occur in SSA with 75 percent of those deaths due to postpartum hemorrhage (PPH). Other causes of maternal mortality include infections, preeclampsia, and delivery-related issues.

Across the globe and specifically in SSA, stable and resilient supply chains for quality-assured maternal health (MH) products are crucial to reducing maternal mortality. United States Pharmacopeia (USP) and the Reproductive Health Supplies Coalition (RHSC) conducted a landscape analysis to assess the demand for and manufacturing capacity of the following five essential MH commodities: heat-stable carbetocin (HSC), magnesium sulfate, misoprostol, oxytocin, and tranexamic acid (TXA). The study analyzed supply and demand across eight focus countries in SSA: Ethiopia, Ghana, Kenya, Nigeria, South Africa, Tanzania, Uganda, and Zimbabwe. In summary, six manufacturers were identified spanning four countries (Ethiopia, Kenya, Nigeria, and South Africa) actively involved in

the production of MH products. Most of these companies have only one MH product in their portfolio. Juhel Nigeria Ltd stands out as the exception, producing two essential MH products: magnesium sulfate and oxytocin.

Overall, magnesium sulfate emerges as the predominant MH product manufactured in the region. It is produced by four manufacturers in four different countries: Nigeria, Ethiopia, Kenya, and South Africa. All four manufacturers are engaged in secondary manufacturing—they all formulate and package the FPPs. None of the identified manufacturers are limited to only packaging services, a sign of the growing maturity of the industry in SSA as compared to previous decades. There was no manufacture of heat stable carbetocin in SSA.

Oxytocin

Juhel Nigeria Limited specializes in the local production and distribution of oxytocin in Nigeria. It is the only manufacturer currently producing this MH product in SSA. The strength of the sterile injectable produced is 10 IU/2ml. The manufacturer's production process relies on importing essential inputs from India, China, and the European Union (EU). In common with other manufacturers in the region, this company procures some of its packaging materials locally. Specifically, primary packaging materials are sourced from the EU, while secondary packaging materials are obtained from local vendors and manufacturers.

This manufacturer's annual production volume fluctuates significantly, presenting a challenge to accurately estimate it. This fluctuation is primarily driven by the unpredictability of orders and the need to utilize the same equipment for the manufacturing of other products, which significantly affects the consistency of oxytocin's yearly output. The overall market demand exceeds the company's production capacity to such an extent that it remains unquantified. Nevertheless, the manufacturer ensures the production of at least 600 kg of oxytocin per year. It is important to note that the manufacturer faces significant logistical challenges to scaling up its oxytocin supply, particularly related to technical expertise in maintaining and repairing cold chain equipment.

Misoprostol

Misoprostol registered with the NMRAs in the eight countries considered is primarily sourced from manufacturers based in Bangladesh, Canada, China, India, the Netherlands, Nigeria, Spain, the UK, and the United States of America. Specifically, three suppliers from India, two from China, one from Bangladesh, and one from the UK seem to be the primary sources of misoprostol for the countries we reviewed. The standard registered strength across these countries is 200 mcg in an oral solid dosage. However, Nigeria and Kenya also have authorized the supply of a 25-mcg tablet.

An interesting observation is that only one Nigerian manufacturing company, Emzor, has successfully registered its misoprostol product in Nigeria, making it the only misoprostol manufacturer in the country and in the region. Notably, none of the focus countries considered have registered misoprostol produced in any other African nation, including the Nigerian manufacturer. This highlights the significant reliance on imports for this crucial medication.

Emzor specializes in the formulation and distribution of 25 mcg and 200 mcg tablets. This manufacturer relies on imports from China for its APIs, and it sources excipients from India and China. Notably, this company stands out as one of the two local producers identified in this study that procures packaging materials from the local market. In the event of a substantial surge in demand, the manufacturer may find it necessary to expand its existing facility or even consider constructing a new plant.

Given the potency of the product, it is imperative that this manufacturing facility remains dedicated and rigorously controlled to prevent any risk of cross-contamination with other production units and personnel.

Magnesium sulphate

The strength of injectable magnesium sulfate available in Sub Saharan Africa (SSA) is 50% w/v (500 mg magnesium sulfate heptahydrate per mL). National Medicines Regulatory Authority (NMRAs) in Ethiopia, Kenya, Nigeria, and Uganda have registered multiple brands, with ten, six, eight, and three registrations respectively, in each country. Indian manufacturers have the most registered magnesium sulfate in Ethiopia, Kenya, Tanzania, and Uganda, accounting for 67 to 100 percent of the registrations.

The NMRAs of Ethiopia, Kenya, Nigeria, and South Africa have each registered a product from a manufacturer operating in their respective countries. However, none of these manufacturers has their product registered in any other SSA country. Four manufacturers of magnesium sulfate in SSA: Humanwell Pharma in Ethiopia, Laboratory and Allied Health in Kenya, Juhel Nigeria Ltd in Nigeria, and Adcock Ingram in South Africa. All the manufacturers produce finished pharmaceutical products (FPP) and package the products themselves. Two of the manufacturers independently developed their products, while one relied on technology transfer for product processing. Manufacturers source their APIs from India, China, or the Czech Republic. The FPP produced across all the manufacturers is the 50 w/v sterile solution form of magnesium sulfate.

Manufacturers strong ask is for access to regional markets through harmonization of regulatory frameworks, trade policies and activation of regional procurement mechanisms.

B. Newborn: Birth asphyxia and birth trauma

Medical oxygen

Oxygen is critical for treating a number of life-threatening conditions such as pneumonia, asthma, chronic obstructive pulmonary disease (COPD), neonatal respiratory syndrome, and pulmonary hypertension.[163] In SSA, these conditions collectively account for an estimated 1.75 million deaths each year. Several countries in SSA import oxygen to satisfy their needs for medical and industrial oxygen.[164]

During the pandemic, African leaders repeatedly called for greater investments in medical oxygen. The President of South Africa, Cyril Ramaphosa, who heads the African Union Commission on the COVID-19 Response, intensified efforts to close the oxygen capacity gap by targeting areas of need while engaging oxygen manufacturers. The UN Economic Commission for Africa (UNECA) has prioritized local medical oxygen production as part of the Pharmaceutical Initiative anchored by the African Continental Free Trade Area, and health leaders, including Dr John Nkengasong, have described local production of critical health commodities as key to Africa's capacity to take charge of its own health security.

Further, the African Medical Supplies Platform has prioritized respiratory care among its product offerings and many innovative oxygen access initiatives have emerged across the continent, tapping local expertise and entrepreneurial talent, including OpenO2, Hewatele, the Oxygen Hub, HealthPort Africa, GLOMED Technologies, OxyMed Global Solution, LifeBank, MGPS, Acuitas, the Oxygen Alliance, and more[165].

To support this continental effort, international agencies, including the members of the ACT-Accelerator Oxygen Emergency Taskforce, which is chaired by Unitaid, have provided grants and loans to help many governments urgently buy the oxygen equipment needed to treat COVID-19 patients, including oxygen plants and cylinders, mobile concentrators, pulse oximeters, ventilators, patient monitors, and more.

But despite all of this, major gaps remain that put many health systems at risk of further oxygen shortages. Oxygen equipment is arriving without the trained staff to operate it and the technicians to maintain it. Most countries have oxygen equipment lying idle

waiting for a spare part and/or trained technicians to repair it. Despite the availability of liquid oxygen for industrial purposes in many nations, access by public hospitals is limited by a lack of critical infrastructure (e.g., piping and storage), and transportation. Governments with national oxygen plans do not have the financing needed to implement them.[166]

To reach a meaningfully large population, including in rural areas, an extensive decentralized oxygen infrastructure will be needed, with networks of, smaller pressure swing adsorption (PSA)[167] plants or cryogenic distillation plants that produce liquid oxygen (LOX)[168] bulk storage sites replenished regularly via trucks from a central LOX production facility.

C. Child health: Antidiarrheals

ORS+Zinc tablets

Diarrhea is responsible for the death of more than 90% of under-five children in low and lower-middle income countries. Regionally, South Asia and sub-Saharan Africa accounted for 88% of deaths. Sixty per cent of these deaths occur in just 10 countries in Asia and Africa: Bangladesh, the Democratic Republic of Congo, Ethiopia, India, Kenya, Niger, Nigeria, Pakistan, Tanzania, and Uganda. One of the main reasons why the death rate from diarrhea is so high in these regions is because the prevalence of diarrhea is associated with high-risk factors such as malnutrition, unsafe water sources, and the lack of access to essential treatment[169].

ORS is a simple product to produce but currently, there are no prequalified ORS products available. Manufacturers consider ORS and zinc to be of limited commercial value as they are low-priced and low-profit margin products. There is also low product utility as over 30% of children with diarrhea are treated at home with some allopathic treatment and ORS is an over-the-counter medication and is marketed socially in many countries. Current indicative pricing for ORS and zinc has significantly decreased over the past three years by an average of eight per cent, notably for the one litre sachets, and zinc on account of economies of scale following an increased supplier base and more competition from importers. Current vendors for ORS include Universal Corporation Limited (Kenya), KBI Pharma (Germany), FDC (India), Eskayef Pharma (Bangladesh) & Renata (Bangladesh). Vendors for Zinc: Nutriset (France), Square Pharma. (Bangladesh), & Macleod Pharma. (India)[170]

Rotavirus
Diarrhoeal diseases are both preventable and treatable, and yet remain the second leading cause of under-five mortality, globally, killing an estimated 525,000 children under five years of age annually. Rotaviruses alone are responsible for 25 to 50 per cent of all severe diarrhoeal cases worldwide, of which 90 per cent occur in Africa. Thus, sub-Saharan Africa carries >80% of the global rotavirus mortality with only 8 countries bearing approximately 80% of that burden (Nigeria, Democratic Republic of the Congo, Niger, Chad, Burkina Faso, Core d'Ivoire, Ethiopia, and Uganda) For the majority of the African countries GAVI continues to drive RV support through UNICEF procurement. The Gavi market has three suppliers as of 2020. Bharat, GSK, and Serum Institute India. Currently, there isn't a pre-qualified manufacturer of RV in SSA.

Growing need high market
A . Stroke

Atorvastatin
Atorvastatin, a crucial medication for lowering cholesterol and preventing cardiovascular disease, presents a compelling case for prioritized production in Africa. While the continent has the technical capacity to manufacture generic versions, challenges remain in accessing technology transfer, securing key inputs, and establishing robust regulatory oversight. However, the supportive policy environment focused on addressing non-communicable diseases and the absence of intellectual property barriers creates a promising foundation.

Valsartan

Valsartan, an angiotensin II receptor blocker, is a crucial medication for treating hypertension and heart failure, effectively reducing the risk of cardiovascular events. This is particularly relevant for Africa, which is facing a rising burden of non-communicable diseases, especially hypertension. Local production of valsartan could have a significant positive impact on the health of millions of people across the continent.

While valsartan production is feasible in Africa, with several countries possessing the capacity to manufacture generic versions, several challenges exist. Technology transfer for valsartan production is not readily available. Furthermore, key inputs for valsartan production are often unavailable and thus imported.

African regulatory agencies may also lack the necessary capacity to effectively oversee the production of ARBs like valsartan, ensuring quality and safety standards. Additionally, the economic viability of local valsartan production has yet to be fully established.
Despite these challenges, there are compelling reasons to prioritize local valsartan production. The policy environment in Africa is supportive of valsartan production, recognizing its importance in combating NCDs. Furthermore, the absence of intellectual property rights for valsartan removes a significant barrier to local production.

B . Injuries

Intravenous Fluids
IV fluids are a critical requirement for delivering medications directly into the bloodstream for faster absorption, critical care for trauma and surgery, correcting electrolyte imbalances, managing sepsis, supporting patients with kidney failure, and even providing nutritional support. However, the high demand for IV fluids is currently met by limited local production due to the inherent risks associated with manufacturing these products. Currently, only one manufacturer in the East African Community produces IV fluids, leading to a single regulatory agency having the capacity to oversee the process of IV manufacture. This limited capacity thus makes it crucial to prioritize the development of local IV fluid manufacturing capabilities. Investing in local production offers significant benefits, the high demand for IV fluids presents a strong market opportunity for local manufacturers. Furthermore, building local capacity will not only strengthen the supply chain but also enhance regulatory oversight.

C. Diabetes

Metformin
Metformin, a vital medication for managing type 2 diabetes, presents a strong case for prioritized production in Africa. The continent possesses the capacity to manufacture generic versions of this essential drug, which is crucial for improving blood sugar control and reducing the risk of diabetes-related complications. However, challenges exist in accessing technology transfer for production, sourcing key inputs, and ensuring robust regulatory oversight. While the market for locally produced Metformin is not yet fully established, the supportive policy environment and the absence of intellectual property barriers offer a good foundation for local manufacturing.

Insulin

Insulin, a life-saving medication for individuals with type 1 diabetes and some cases of type 2 diabetes, presents a unique challenge for local production in Africa. While the need for insulin is substantial, the complex manufacturing process requires specialized facilities and expertise, making local production less feasible compared to other medications.

While technology transfer for insulin production is readily available, the lack of readily available key inputs, such as purified insulin, necessitates reliance on international suppliers. Furthermore, the regulatory landscape in Africa needs significant development to ensure the production of highly sensitive medications like insulin meets stringent quality and safety standards.

D . IHD/ Hypertension

Amlodipine

Amlodipine, a highly effective calcium channel blocker, plays a crucial role in treating hypertension, a major risk factor for cardiovascular disease (CVD) in Africa. This is particularly urgent given the growing non-communicable disease (NCD) epidemic on the continent, where heart attacks, strokes, and other cardiovascular complications are on the rise. While Africa has the potential to manufacture amlodipine, several challenges hinder its realization.

Firstly, technology transfer for amlodipine production is not readily available, making it difficult to establish local manufacturing capabilities. Secondly, key inputs required for amlodipine production are often unavailable in Africa, creating dependencies on imports. Furthermore, African regulatory agencies may not be fully equipped to oversee the production of essential medicines like amlodipine, ensuring quality and safety standards.

Despite these challenges, there are compelling reasons to prioritize local amlodipine production. The policy environment in Africa is increasingly focused on addressing NCDs, favouring the production of essential medicines like amlodipine. Additionally, the absence of intellectual property rights for amlodipine removes a significant barrier to local production.

Growing need low market
A . Sickle cell disease

Hydroxyurea

Sickle cell disease is an inherited haemoglobin disorder and is the most common genetic condition in the WHO's African region[172]. This region bears the highest global burden of the disease, with a prevalence rate of 2% and 38,403 reported deaths in 2019[173]. Approximately 50–80% of the estimated 400,000 infants born with sickle cell disease each year in Africa do not survive past the age of five[174]. The disease primarily affects Africans, it is crucial to intensify efforts to manufacture hydroxyurea locally. This initiative would significantly improve health outcomes and provide essential treatment options for those in need.

The conditions in the region highlight that existing national policies and strategies are insufficient; there is a lack of appropriate facilities and trained healthcare professionals[175] , as well as inadequate diagnostic and treatment options.

Low need high market
A . Anticancer agents: Docetaxel

Hydroxyurea

The potential market in East Africa is growing as cancer cases rise. Prices are known to be a constraint on access to care. Recent international initiatives to try to increase access to cancer medicines in Sub-Saharan Africa have not, to date, gone down this route of supporting local production. As with previous global disease-focused initiatives, the focus has been on reducing the price of imported medicines, with philanthropic support.

In 2017 the BMJ reported (Dyer, 2017, cited also in WHO, 2018b, p. 36) on an agreement negotiated by the American Cancer Society and the Clinton Health Access Initiative with Pfizer and Cipla to provide "at or near production cost price" to Ethiopia, Kenya, Nigeria, Rwanda, Uganda and Tanzania the following cancer drugs: docetaxel, doxorubicin, epirubicin, fluorouracil, gemcitabine, leucovorin, methotrexate, and

paclitaxel (Pfizer); anastrozole, bleomycin, capecitabine, cytarabine, and vinblastine (Cipla); and carboplatin, cisplatin, and oxaliplatin (both). This was described as “a sustainable model of philanthropy[176]

In 2021, an expanded “Cancer Access Initiative” was announced, with four companies: Biocon Biologics (an Indian biotech), Novartis and Pfizer (innovator companies), and Viatris. The stated aim of the initiative is to generate savings of 60% on the purchase by low- and middle-income countries’ governments of chemotherapy and hormonal medication for 30 cancers including a range of breast cancer regimens.

These initiatives, which involve no technology transfer to African producers, also raise questions about sustainability, and the extent to which they could help to address health security concerns in crises including the recent pandemic and the next[178].

For African cancer care, which oncology products are currently the most important for ensuring continuous high-quality supply at low cost? This question can feel invidious since all products are important to particular patients when that is what they need. However, some oncology products are “workhorses” with many applications. The WHO has developed, and regularly updates, a list of essential cancer medication (WHO, 2021b). For analysis of trade and pricing, a selection of a subset of these, drawn from two East African expert sources cyclophosphamide, methotrexate, Fluoro Uracil (5FU), doxorubicin, docetaxel, paclitaxel, gemcitabine, etoposide, cisplatin were identified as local oncologists priority medicines and they also were given same priority by local manufactures as potential agents for local production[179].

Low need low market
A. NTDs

Praziquantel

Praziquantel is a vital medication for treating schistosomiasis, a parasitic disease that disproportionately affects the poorest populations in Africa. This poverty-related disease often falls outside the focus of major pharmaceutical companies, highlighting the need for Africa to take ownership of its health solutions.

Fortunately, there are encouraging signs of progress. Technology transfer for praziquantel production is already present, particularly in Kenya, with a specific focus on paediatric formulations. This is a crucial step, as schistosomiasis heavily impacts children. Furthermore, Merck, a major pharmaceutical company, has expressed interest in this product. This engagement, combined with the efforts of global health initiatives like The Paediatric Praziquantel Consortium, which aims to reduce the global burden of schistosomiasis in children under six years old, provides a strong foundation for prioritizing local manufacture of praziquantel in Africa.

3.6 Medical products for consideration for future manufacturing
High need low market

A . Maternal Health

Tranexamic acid

India-based manufacturers seem to dominate the TXA market in SSA. The registration records in nearly all the countries reviewed indicate that an Indian manufacturer accounts for at least 60 percent of the registered TXA in Ghana, Kenya, Nigeria, South Africa, Tanzania, Uganda, and Zimbabwe. Three Pakistani companies also seem to play a significant role in the supply of TXA in Kenya, Tanzania, Uganda, and in Nigeria.

The registration records of TXA in the region suggest that a nearly even number of injectables and tablets are available throughout SSA, although the proportion differs depending on the country. For example, the injectable form of the drug appears to be the most registered in Ethiopia and Tanzania (more than 90 percent), while in Uganda and Zimbabwe there is an even split between tablets and injectables. The most prevalent strength is 500 mg/5ml, accounting for 66 percent of all registered products in SSA. The 100 mg/ml and 250 mg/5ml account for 21 percent and 11 percent of the registered products, respectively.

Only one manufacturer in Kenya (Tasa Pharma) has registered TXA with the country's NMRA and is currently producing the MH product in SSA. Tasa Pharma is a new start-up that aims to produce more MH products. It is currently producing 500 mg/5ml glass ampules of TXA. The company relies on imports from India for its APIs (CEP certified, according to the manufacturer). Its excipients come from the EU, and packaging materials are sourced from India. The company developed its product in-house and has begun producing TXA with an annual production of approximately 800 kg or 1,600,000 ampules. Several batches are currently being produced and packaged in blisters of five or ten 10 ml ampules. Equipment challenges, including the limited size of autoclaves, hinder the possibility of scaling production.

However, the South Africa-based company discontinued its production line due to the loss of tender a couple of years ago. This highlights the fragility of the market for manufacturers due to competition from imports and the need to design policies to boost demand.

Heat stable carbetocin (HSC)

HSC is registered in Ethiopia, Ghana, Kenya, Nigeria, Tanzania, and Uganda; the products registered are from companies based in Germany and China. The registered strength of the injectable form is 100 mcg/ml. The limited registration of the product is largely due to the slow progress toward updating the national PPH guidelines and EMLs since policy updates precede regulatory approval of HSC in most SSA countries.

The landscape analysis identified no manufacturers of HSC in the region. Although the primary patent on carbetocin has expired, there are patents or patent applications on the heat-stable formulation in several countries that are current until 2031.[180] Therefore, no manufacturer in SSA can produce HSC without a licensing agreement with the patent holder. Even with a licensing agreement, with the current level of uptake on the Continent, most manufacturers will struggle to make a business case for the production of HSC within the region because of the small size of the current market and the availability of current manufacturers.

Condoms

The availability and affordability of condoms in Africa are crucial for reducing the spread of HIV/AIDS and other sexually transmitted infections (STIs), as well as preventing unintended pregnancies. Condoms offer triple protection, yet a significant gap exists between supply and demand, particularly in sub-Saharan Africa. This gap, exceeding 3 billion condoms annually.[181] , hinders progress towards achieving the 2030 Sustainable Development Goals related to health, including ending the AIDS epidemic and ensuring universal access to sexual and reproductive healthcare.

Despite Africa's rubber production, condom manufacturing remains limited, with only five manufacturers producing less than 10% of the continent's needs[182]. Furthermore, none of these manufacturers meet the pre-qualification standards set by the WHO and UNFPA, limiting their participation in global procurement.[183]

The need for increased condom manufacturing in Africa is a critical health and economic imperative that should not be delayed.

High need High Market
A . HIV/AIDS

HIV Vaccine

While the HIV epidemic continues to impact Africa, a vaccine remains a long-term goal, still under development. While the need for an HIV vaccine is high, local manufacturing faces significant challenges.

Feasibility is poor, technology transfer and intellectual property rights would need to be negotiated, and key inputs are currently unavailable. This presents an opportunity to push for research and development (R&D) on the continent. Regulatory agencies are not yet equipped to oversee HIV vaccine manufacture, and the economic market is not yet established. However, focusing on clinical trials could be a starting point.

Global health initiatives like IAVI, NIH, UNITAID, and PEPFAR are already pushing for HIV vaccine development. Therefore, considering the future local manufacturing of an HIV vaccine in Africa is crucial.

Malaria Vaccine

Malaria continues to devastate Africa, claiming 94% of global cases and 95% of deaths))[184], with children under five bearing the brunt of the burden[185]. While traditional interventions like insecticide-treated nets and artemisinin-based therapies remain vital, the recent approval of the RTS,S/AS01 malaria vaccine offers a glimmer of hope. This vaccine, recommended by the WHO for children in high-transmission areas provides partial protection against malaria [186]. The vaccine has reached nearly 2 million children in Ghana, Kenya and Malawi through the Malaria Vaccine Implementation Programme, MVIP, since 2019.[187]

Despite this progress, significant challenges remain. Limited access to the vaccine, particularly in remote areas, hinders its impact. Moreover, ongoing research is crucial to combat this deadly disease and protect children in Africa.

Low need high market
A. Hepatitis B Vaccine

Viral hepatitis poses a significant public health threat in Africa, affecting over 91 million people, with 82 million living with HBV and 9 million with HCV[188]. In 2019 alone, an estimated 990,000 new HBV infections and 210,000 new HCV infections occurred, resulting in 80,000 HBV-related and 45,000 HCV-related deaths. In the WHO African Region, only 2% of people with hepatitis B are diagnosed. Despite these alarming figures, HBV vaccine birth dose coverage in 2021 was only 17%, lagging behind the global average of 42%. This highlights the urgent need for increased vaccine access and implementation of effective strategies. Encouragingly, 29 African countries developed national hepatitis strategic plans in 2021, demonstrating a commitment to tackling this public health challenge.

The WHO has set a global target to reduce new Hepatitis B infections by 90% by 2030. This target cannot be achieved without prioritizing vaccine manufacturing and access in high-burden regions like Africa.

Several initiatives, such as the Global Vaccine Action Plan (GVAP) and the African Regional Immunization Strategy (ARIS), emphasize the need for increased vaccine production and access to achieve universal immunization.

4 Conclusion and Recommendations

A priority list of medical products can enhance local pharmaceutical manufacturing in Africa by creating focus, harmonising resources and development. To maximize the impact of these efforts, African regional and continental institutions should conduct a thorough assessment of the remaining gaps within the value chains of the prioritized products. This analysis will help identify areas where additional funding and support are needed to ensure a coordinated and effective approach. By leveraging the work of existing partnerships and addressing the identified gaps, it is possible to accelerate progress towards a more sustainable, regional manufacturing sector in Africa. This will not only improve access to affordable medical products but also contribute to the economic development and self-sufficiency of African nations.

Implementation of a roadmap for the Priority medical products list will require concerted political will. Below are recommendations to be emphasised:

1. Prioritisation of manufacturing of High-Need, High-Market Products with a focus on infectious diseases such as HIV/ AIDS, TB, malaria, and pneumonia. However, given the growing burden of non-communicable disease, there is a need to increase the production of medical products for conditions like diabetes and hypertension.

2. Investments in Research and Development (R&D): Support for local innovation to develop new and improved products, particularly for African-specific diseases and conditions. Investments are required in collaborations with international partners, multinational companies and research institutions to transfer technology and knowledge.

3. Strengthen Regulatory Frameworks: African countries should work towards harmonized medicines regulations across the continent to create a level playing field for manufacturers while building the capacity of regulatory authorities through investments in training.

4. Improve Access to Raw Materials and Inputs: African countries should promote local production of APIs to reduce reliance on imports and mitigate supply chain risks. African traditional medicines could provide more secure, reliable and affordable sources of raw materials.

5. Facilitate Market Access by implementing policies and incentives to attract investment and support to local manufacturers. RECs should leverage economies of scale and enhance competitiveness by adopting regional manufacturing hubs.

6. Address IPRs barriers by optimising IPR policies to promote local manufacturing while protecting public

health interests. There is a need to leverage the flexibilities provided by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

7. Enhance Human Capital Development: investments in education and training for skilled labour in pharmaceutical manufacturing and encourage a culture of innovation and entrepreneurship within academia and the pharmaceutical sector.

8. Strengthen Public-Private Partnerships through collaborations with multinational companies to transfer technology, provide technical assistance, and access global markets.

9. Improve Infrastructure and Logistics in cross-continent transportation/ supply chain management systems, energy, and communication infrastructure to support the pharmaceutical industry.

4.1 Regional Pharmaceutical Value Chains in Africa

The pharmaceutical value chain is the interconnected flow of activities in the development, production, distribution, consumption and post market surveillance of pharmaceutical products. It has seven seven stages as below:

1. Research and Development: includes Drug discovery which is identifying potential therapeutic compounds and Preclinical testing which is the testing of potential therapeutic compounds in laboratory and animal models to assess safety and efficacy.

2. Clinical Trials: testing of safety and efficacy of pharmaceuticals in the human population in three stages:

- Phase I: Testing of pharmaceuticals in healthy human volunteers to assess safety.
- Phase II: Testing of pharmaceuticals in a small group of patients with the target disease to assess efficacy and safety.
- Phase III: Testing of pharmaceuticals in a large group of patients to confirm efficacy and safety and to identify potential side effects.

3. Regulatory Approval: Registration/ application made by pharmaceutical companies to NMRAs for market approval and entry of pharmaceutical products into a country.

4. Manufacturing: there are three forms of manufacturing:

- Active Pharmaceutical Ingredient (API) Production: Manufacturing the core/ active components of the drug.
- Formulation: Combining the API with excipients to create the final pharmaceutical product.
- Packaging: of pharmaceuticals in appropriate containers.

5. **Distribution of pharmaceuticals** by wholesalers to retailers.

6. **Prescribing and dispensing** of pharmaceuticals by healthcare providers and service delivery points to patients.

7. Consumption and monitoring: includes the use of pharmaceuticals by patients monitoring of the patients for adverse effects and adjusting treatment as needed by healthcare providers and post market surveillance.

The pharmaceutical value chain in Africa is currently dominated by the stages of distribution and consumption. The development of local pharmaceutical manufacturing capabilities in Africa is expected lead to a shift in the value chain over time.

Regional African pharmaceutical value chains can play a crucial role in promoting local production, improving access to essential medicines, and creating jobs. By fostering collaboration and integration among countries, these chains can help to reduce costs, increase efficiency, and enhance the quality of pharmaceutical products.

Below is a highlight of Regional pharmaceutical value chains in Africa:

1. Research and development institutions:

These are organizations that conduct research and development to develop new pharmaceutical products and improve existing ones.

Africa's contribution to global research is a meagre 2% yet it accounts for 15% of the global population and bears 25% of the global disease burden[189]. The research and development pipelines for diseases that disproportionately affect African countries and address their unmet health needs are insufficient[190]. More needs to be done to bridge this significant gap.

The University of Cape Town's Holistic Drug Discovery & Development (H3D) centre stands as a unique example in Africa, serving as the continent's only integrated platform for drug discovery and development[191]. While Africa boasts a growing research landscape, with over 250 research sites and 73 vaccine clinical trials, significant gaps remain[192]. The continent faces a shortage of specialized expertise, with fewer than 10 universities offering vaccinology courses and only two engaging in pre-clinical vaccine research[193]. This underscores the need for continued investment and development to strengthen Africa's capacity in this critical area.

Supporting research and development can help to drive innovation and create new opportunities for regional value chains.

2. Raw materials suppliers:

Raw materials used in pharmaceutical production, include active pharmaceutical ingredients (APIs), excipients, and packaging materials. Despite Africa being rich in a diverse range of natural resources, including minerals, metals, plant and animal biodiversity, and energy sources, most raw materials (up to 95%) used in pharmaceutical industry are imported. For example, there are only three API manufacturers —two in South Africa, and one in Ghana— and none have significant R&D activity[194].

Investment is required to develop infrastructure in exploration, extraction, processing, transport, storage, and processing facilities for efficient raw material production. Adoption of modern technologies will be essential in improving productivity and efficiency in raw material production.

3. Manufacturing facilities:

Pharmaceutical manufacturers in Africa range from small-scale contract manufacturing organizations (CMOs) to large-scale multinational pharmaceutical companies and focus on generics. Up to a hundred manufacturers in sub-Saharan Africa (approximately 25% of facilities on the continent) are limited to importing finished drugs in bulk and repackaging them into consumer-facing containers (fill and finish)[195]. Therefore, there is an opportunity for a gradual strengthening of the capacity of facilities.

Most sub-Saharan African manufacturers are small privately-owned firms that serve national markets. There are a few publicly listed companies but increasingly foreign firms are establishing large firms using international equity finance (e.g., Universal Corporation Ltd. in Kenya). There are also a few Indian and Chinese multinationals such as CiplaQCIL in Uganda, Humanwell Healthcare Group in Mali and Sansheng Pharmaceuticals PLC in Ethiopia.

The manufacturers produce mostly simple formulations such as tablets, capsules, lotions, and suspensions for a limited range of products, restricted to over-the-counter formulations and basic prescription medicines covering cough and cold preparations, vitamins, analgesics, basic sedatives, anti-malarial, anti-helminthic, older generation antibiotics, first generation anti-hypertensives, anti-diabetics, first-line and second-line antiretroviral medicines. Very few local companies produce advanced formulations such as sustained release tablets, and complex products, such as immune sera and immunoglobulins, sterile products and vaccines while expensive innovative medicines such as anticancer drugs, immunosuppressive drugs, and blood components are imported[196].

4. Supply chain networks:

Supply chain networks are distribution systems responsible for delivering pharmaceutical products to healthcare facilities and patients.

Africa Development Bank has described supply chain systems in Africa as being fragmented. Some reports have also highlighted the difficulty and high logistical costs of moving pharmaceutical inputs . AfDB has proposed the establishment of four pharmaceutical hubs based on regional proximity to facilitate logistics, facilitate pharmaceutical trade integration and enhance competitiveness[198].

The four potential hub locations are: West Africa, South Africa, East Africa, and North Africa. Within each hub, specific countries are identified as potential nerve centres based on their manufacturing and logistics capabilities. These countries will play a crucial role in coordinating pharmaceutical trade within their respective hubs. The hubs are aligned with existing regional economic communities (RECs) in Africa, such as the Economic Community of West African States (ECOWAS) and the Southern African Development Community (SADC). This alignment will help ensure that the hubs are integrated into the broader regional economic framework. The nerve centres within each hub are well-connected and integrated to effectively supply their respective regions with pharmaceuticals; this will involve improving infrastructure, logistics, and regulatory frameworks. The North African hub is expected to have a different focus, primarily serving as a hub for exporting pharmaceuticals to the entire African continent. This could be due to its proximity to Europe and its existing pharmaceutical industry.

The alignment of the hubs with regional economic communities (RECs) implies that they will be involved in coordinating and harmonizing regulatory frameworks. This is essential for ensuring that pharmaceutical products can move freely between countries within the hubs without facing unnecessary barriers.

By promoting regulatory harmonization, the hubs can help to create a more predictable and efficient environment for pharmaceutical trade, which will ultimately benefit patients and healthcare providers across Africa.

Potential Hubs and Their Nerve Centres:

- **West Africa:**
  - Potential nerve centres: Côte d'Ivoire, Senegal, Ghana, Nigeria
  - Potential hub members: Benin, Gambia, Angola, Mozambique, Burundi, Mauritania, Guinea, Botswana, Libya, Burkina Faso, Namibia, Comoros, Cameroon, Guinea-Bissau, Zimbabwe, Cabo Verde, Liberia, Congo, Eritrea, Eswatini, Central African Republic, Mali, Lesotho, Seychelles, Chad, Niger, Somalia, Gabon, Sierra Leone, Madagascar, South Sudan, Malawi, Togo, Sudan
- **Southern Africa**:
  - Potential nerve centre: Mauritius, South Africa, Zambia
  - Potential hub members: Angola, Botswana, Lesotho, Malawi, Mozambique, Namibia, South Africa, Eswatini, Zambia, Zimbabwe
- **East Africa**:
  - Potential nerve centres: Ethiopia, Kenya, Rwanda, Tanzania, Uganda
  - Potential hub members: Burundi, Comoros, Djibouti, Eritrea, Madagascar, Mauritius, Seychelles, Somalia, South Sudan
- **North Africa**:
  - Potential nerve centres: Algeria, Egypt, Libya, Morocco, Tunisia
  - Potential hub members: Algeria, Egypt, Libya, Morocco, Tunisia

The hubs are intended to be well-connected and integrated into their respective regions to supply their needs. The North African hub will have a different purpose, primarily aiming to export to the entire continent.

Africa ought to address intra-continent supply chain challenges to build resilience into regional value chains and mitigate the impact of disruptions, such as pandemics or natural disasters.

5. Regulatory bodies:

NMRAs are government agencies that oversee the quality, safety, and efficacy of pharmaceutical products and ensure compliance with regulatory standards. As has previously been elucidated in this report, more than 90% of NMRAs have either minimal or no capacity and do not meet international standards [199'200] . The regulatory environment is fragmented, with various stakeholders working independently, leading to inefficiencies and inconsistent practices across the continent[201]. Regional initiatives such as ZAZIBONA, the East Africa Community Medicines Regulatory Harmonization Programme; continental initiatives such as AVAREF, and AMA and global initiatives such as the WHO Prequalification Scheme have strengthened regulatory capacities across the continent[202]. However, more ought to be done to work towards harmonized regulatory frameworks across countries. This will reduce trade barriers and facilitate the flow of goods across the continent.

6. Healthcare providers:

These are consumer facing entities that provide last mile for pharmaceutical products. They include hospitals, clinics, and pharmacies that prescribe and dispense pharmaceutical products to patients.

Africa is not a lucrative pharma manufacturing market as most of the population is still paying for medicines out of pocket. Out-of-pocket payments, the predominant form of health care financing in sub-Saharan Africa place a heavy financial burden on individuals, particularly the poor, and often lead to delayed or forgone treatment[203]. As long as people are still paying for medicines, the market is low.

However, a paradigm shift is underway. Governments across Africa are increasingly recognizing the need for universal health coverage (UHC) and are implementing health insurance schemes [204]. Several African countries have made notable progress in implementing health insurance programs. Rwanda, for instance, has achieved near-universal health coverage through its community-based health insurance scheme[205]. These schemes aim to pool resources, reduce financial risk, and improve access to essential healthcare services, including medicines. This shift towards health insurance presents a significant opportunity for the pharmaceutical industry. As more people gain access to affordable healthcare, demand for medicines will rise, creating a more stable and attractive market for investors.

Key strategies to improve regional value chains in pharmaceutical production are further underscored below:

- The African Union should encourage collaboration among governments, businesses, and research institutions to identify and address shared challenges and opportunities.
- The African Union should support governments and training institutions to develop human capital through investments in training and capacity-building programs to develop skilled workforce needed to support regional value chains.
- The African Union should support countries to address Intellectual Property Rights gaps by developing effective intellectual property rights regimes to utilise the Flexibilities of the TRIPS Agreement, protect innovation and incentivize investment in research and development.
- The African Union should facilitate access to affordable financing to help businesses to invest in the necessary infrastructure and equipment to participate in regional value chains.
- The African Union should support governments with public-private partnership frameworks with privately owned enterprises which are currently playing a vital role in regional value chains, to be provided with technical assistance, training, and access to markets to support their growth and development.

By implementing these strategies, African countries can work together to build strong and sustainable regional value chains in the pharmaceutical sector, leading to increased local production, improved access to medicines, and economic growth.

4.2 Roadmap for the Priority List of Medical Products for Pharmaceutical Manufacturing in Africa

2025-2030

4.2.1 Goal

Develop a self-sufficient, sustainable and resilient pharmaceutical manufacturing ecosystem in Africa, ensuring at least 50% of the continent's pharmaceutical needs are met locally.

4.2.2 Objectives

1. Secure political commitment and policy support to drive the development of a sustainable African pharmaceutical industry.
2. Develop and implement policies to foster technology transfer for local manufacturing of 24 priority medical products on the continent.
3. Strengthen the workforce for local pharmaceutical manufacturing of priority medical products.
4. Promote research and development, and facilitate technology transfer and innovation to support local manufacture of priority medical products.
5. Create an investment climate for local manufacture of priority medical products.
6. Strengthen and harmonize regulatory systems to create a conducive environment for the pharmaceutical industry in Africa.
7. Optimize supply chains and market access for priority medical products.
8. Foster partnerships and collaboration for regional manufacturing of priority medical products.

Objective 1: Secure political commitment and policy support to drive the development of a sustainable African pharmaceutical industry.

Political commitment is required to ensure that countries adopt the priority medical products' list. Heads of State and policymakers are cognizant of the need for a sustainable African pharmaceutical industry to reduce the continent's reliance on foreign pharmaceutical products, ensuring greater self-sufficiency, security and resilience. Adoption of the priority medical products' list will increase development of the pharmaceutical industry, foster innovation, research, and development; improve access to affordable medicines and also create a strong pharmaceutical industry that creates jobs, generates revenue, and reduces dependence on imports.
Collaborations with civil society and the private sector through the Federation of African Pharmaceutical Manufacturers' Association will be important to enhance public awareness and political support for the development of a sustainable African pharmaceutical industry.

Objective 2: Develop and implement policies to promote local manufacture of 24 priority medical products.

Policies are required to incentivize local pharmaceutical production. These may include policies on tax incentives, subsidies, regulatory reforms as well as those for infrastructural development (manufacturing facilities, research and development laboratories, and quality control facilities etc), skills development through training programs and capacity building initiatives; to foster partnerships between governments, industry, and academic institutions to promote collaboration and knowledge sharing and for regulatory harmonization to harmonize regulatory standards and procedures, facilitate trade and investment.

Objective 3: Strengthen the workforce for local pharmaceutical manufacturing of the priority list of medical products.

Lack of skilled labour is one of the factors hindering the growth and development of the pharmaceutical industry in Africa. A well-trained workforce is essential for ensuring the quality and safety of pharmaceutical products and can drive innovation and product development in the sector. Investments in workforce development will economic growth and sustainability of the sector.

It will require development and implementation of training programs to equip individuals in schools and on-job with the skills in quality control and regulatory compliance. Partnership are

proposed between universities, technical institutes, and industry associations to develop relevant curricula and training programs and provision of apprenticeships and internships for students, recent graduates and existing industry personnel to gain practical experience in pharmaceutical manufacturing. AUDA-NEPAD can work with governments and development partners to design and provide incentives, such as scholarships, and stipends to attract and retain talent in the pharmaceutical industry.

Objective 4: Promote research and development, and facilitate technology transfer and innovation to support local manufacture of priority medical products.

Research and development is essential for developing new and improved pharmaceutical products, addressing unmet healthcare needs, and staying competitive in the global market. Access to advanced technologies through technology transfer can help local manufacturers improve their production processes, reduce costs, and enhance product quality. Innovation can also drive economic growth and create new business opportunities.

Objective 5: Create an investment climate for local manufacture of priority medical products.

The pharmaceutical sector is capital-intensive and may not provide quick returns on investment as other sectors can provide. A favourable investment climate is therefore necessary to attract domestic and foreign investors. It requires affordable financing, tax incentives (such as corporate tax breaks, investment allowances, and research and development credits), regulatory reforms (such as simplified and streamlined regulatory procedures), infrastructure development (including secure land, manufacturing facilities, transportation networks, and energy supply, water to support the industry).

Objective 6: Strengthen and harmonize regulatory systems to create a conducive environment for the pharmaceutical industry in Africa.

Harmonized regulations provide investors with greater certainty and predictability, encouraging investment in the pharmaceutical sector. Consistent regulatory standards can reduce trade barriers and facilitate the movement of pharmaceutical products across borders. Strong and harmonized regulations can help ensure the safety, efficacy, and quality of pharmaceutical products, protecting public health.

Objective 7: Optimize supply chains and market access for priority medical products.

Markets in Africa are complicated by disintegrated supply chains, poor road networks and expensive freight charges. Efficient supply chains and expanded market access can ensure that priority medical products reach patients in need, especially in remote or underserved areas in a timely manner thereby enhancing health outcomes and stimulating economic growth for the entire continent.

Investment is required for transportation systems, and infrastructure to improve the efficiency of supply chains. Consideration of supply chain harmonization across RECs through the implementation of a pharmaceutical hub system can significantly reduce trade barriers. It is also important to develop and implement market information systems to track the manufacture, importation and export of priority medical products. Also strengthening of supply chain management practices (demand forecasting, inventory management, and quality control) are necessary.

Cross-cutting objective: Foster partnerships and collaboration for regional manufacturing of priority medical products.

Partnerships and collaborations support the sharing of knowledge, resources, expertise, and facilities, reducing costs and improving efficiencies. Partnerships also facilitate access to larger markets, expanding the reach of locally manufactured pharmaceutical products. Partnerships also promote regional economic integration and development; and increase regional cooperation in the pharmaceutical sector.

Partnerships and collaborations are required across all the objectives and the entire value chain.

Intervention framework

Intervention	Results	Indicator	Responsible entity	Timeline	Cost (USD)
Objective 1: Secure political commitment and policy support to drive the development of a sustainable African pharmaceutical industry.					
1. Establish high-level political platform for advocacy and dialogue	- Stakeholder mapping conducted - Stakeholder engagement framework -Member States Ministers of Health review, provide inputs and recommendations - AU executive Council review, adapt or adopt - Ministers and Heads of State approve list -Head of State to promote political advocacy and dialogue	List of agreed stakeholder list developed -Stakeholder engagement framework in place -No. High-level meetings conducted -AU Ministers' Meeting/ No. countries that endorse Priority list No. of initiatives achieved by the champion	AUDA-NEPAD/ RECs	2025 2025 2025-2030 2025	2,500 5,000 1,000,000 300,000
2. Establish Continental and regional manufacturing platform for advocacy, dialogue and harmonization as regards priority products	- Stakeholder mapping conducted - Stakeholder engagement framework developed -OPS review, have a buy in and recommendations and adapt, or adopt where applicable - AU executive Council review, adapt or adopt	-No. of OPS BUY IN secured	RECs / AUDA - NEPAD	2025 2025-2030	10,000 800,000

	- Countries adapt regional priorities into national policies/plans				
3. **Build strategic partnerships and collaborations with global health initiatives for continental manufacturing**	- Collaborations with private sector eg FAPMA and Civil society organisations - MoUs signed with global health initiatives	-No. Engagements with private sector and CSOs -No. of MoUs signed with global health initiatives	AUDA-NEPAD/ RECs	2025-2030	500,000
4. **Establish PMPA Secretariat to lead the PMPA initiative**	- Coordinator of the CAP in place - PMPA Governance structures operational -Provide quarterly report of activities in a timely manner - Publish monthly/quarterly newsletters	-ToR for Coordinator -No. meetings of the Board, TWGs -Timely submission of quarterly report	AUDA-NEPAD	2025 2025-2030 2025-2030	300,000 600,000 300.000
Objective 2: Promote implementation of local production of 24 priority medical products.					
1. Review and harmonise multisectoral policies for local manufacturing on the continent	- Adopt the Compendium of Good Pharmaceutical Polices Guidelines and Practices and cGMP - Support countries to leverage existing policies on local production to adapt or integrate for expansion of local manufacturing in the continent	- Compendium adopted -No. of additional countries adopting policies	AUDA-NEPAD AUDA-NEPAD/ RECs	2025 2025-2030	200,000 2,000,000
2. **Strengthen/develop AU IP frameworks to support innovation and local production**	- Map countries with IP laws and use them to foster local production - Support countries use of IP for innovation	- No of countries that have utilized IP laws -No. of countries supported	AUDA-NEPAD/ RECS AUDA-NEPAD/ RECS	2025-26 2025-2030	10,000 1,000,000
3. **Facilitate implementation of agreed policy reforms to streamline approval processes**	- Assess regional policies and best practices on approval	- Assessment report	AUDA-NEPAD/ RECS	2025/6	15,000

for locally manufactured products.	process for locally manufactured products - Collaborate with AMA in meetings with national policies to advocate for policy reforms	-No. meetings with RECs/ national policymakers	AUDA-NEPAD/ AMA	2026-2027	800,000
Objective 3: Strengthen workforce for local pharmaceutical production of priority list of medical products.					
1. **Establish a comprehensive list of human resources and skills and define those required along the pharmaceutical manufacturing value chain for priority medicines by region**	A mapping/assessment	-Report - baseline assessment report - needs assessment report - gap analysis.	AUDA-NEPAD/ RECS	2025	10,000
2. **Assess and designate Regional Centres of Excellence (RCEs) for priority medical products manufacturing**	- Assessment to determine RCEs for training - Designate RCEs for training - Set up training collaborations between established Pharma industry ecosystem and local manufacturing sector in the region	-No. of RCEs determined - No of RCEs designated -No. collaborations and partnerships developed and achieved	AUDA-NEPAD/ RECS AUDA-NEPAD/ RECS AUDA-NEPAD/ RECS	2025/6 2026 2026-2030	150,000 10,000 500,000
3. **Develop and implement national, regional and continental -platforms Medical Product Manufacturing**	Establish platform for information sharing and skills development. *Establish e-Learning platform*	No. for e-sharing platform No. trained using e-learning platform -No of countries participating in the e training platform	AUDA-NEPAD AUDA-NEPAD	2025 2025	50,000 50,000
4. **Facilitate on-job training and skills development at country/regional level**	- Secure partner for on-job training	Database on skill developed	AUDA NEPAD & RECS	2025/6	20,000

5. Support development of HR Retention Program	- Assess HR gaps and opportunities - Develop a pharmaceutical industry HR retention program	Assessment report - HR Retention Program developed and disseminated	AUDA-NEPAD AUDA-NEPAD	2025/6 U2026	50,000 100,000
Objective 4: Promote research and development, facilitate technology transfer and innovation to support local production of priority medical products.					
1. Establish 5 Regional collaborative research and development network across Africa	-Members states in each region set up RnD network -Establish regional CROs and research centre Create continental registry for R&D programs	RnD network in place	AUDA-NEPAD	2026/7	20,000
2. Facilitate and coordinate technology transfer partnerships between African manufacturers and global medical products.	Negotiated / established technology-Technology transfer partnerships Manufacturing Partnerships (CMOs)-Establish CDMOs, CMO	-No of strategic Partnerships towards tech transfer agreement -No. of technology transfer partnerships established -No of Tech transfer executed	AUDA-NEPAD/ RECs/ Countries	2026-2030	400,000
3. Establish/ and Develop clusters 5 Innovation hubs to support and SMEs in health product development	- Member states per region set up Innovation hubs developed/ established	- No. of innovation hubs established	AUDA-NEPAD/ RECs/ Countries	2025-2030	1,000,000
4. Support the strengthening of regulatory systems	- Assessment of manufacturers that meet international standards. - Support the improvement of manufacturers to meet internationally recognized standards	- Assessment report - No of manufacturing plants supported	AMA/ AUDA-NEPAD/ RECs AMA/ AUDA-NEPAD/ RECs	2025/6 2025-2030	150,000 3,000,000
Objective 5: Create an investment climate for local manufacture of priority medical products.					
1. Harmonise incentive programs for local and foreign investors	- Map innovative harmonized financing mechanisms/initiatives for local manufacturing.	- Mapping report -Incentive Guide/Framework	AUDA-NEPAD AUDA-NEPAD	2025/26	20,000 20,000

	- Develop framework to guide incentives				
2. Strengthen/establishment of PPPs to mobilize resources for manufacturing	- Support the financing of PPPs - Technical assistance for business management: donors PTF, AFD, BMGF, AfDB, EUTAF; - Capital mobilization and concessional loans: World Bank, EIB, AFREXIMBANK, EQUITY, ECOBANK	Number of funding PPPs strengthened/established	AUDA-NEPAD/ RECs	2025-2030	200,000
3. Improve the legal, regulatory and business environment to facilitate investment	- Map/identify best practices in regulatory and business environment for pharmaceutical investment - Disseminate best practices	- Report No. of best practices leveraged	AUDA-NEPAD AUDA-NEPAD/ RECs	2025/6 2025-2030	15,000 50,000
Objective 6: Strengthen and harmonize regulatory systems to create a conducive environment for the pharmaceutical industry in Africa.					
1-Capacity Building Program for National Drug Regulatory Authorities (NMRA) Build on existing AMRH initiatives on this intervention	- Adoption of the African Union Framework for Harmonization of pharmaceutical regulation - Set up Capacity Building Program for NMRAs	- No. of countries that endorse framework -No. NMRAs that have reached Maturity Level 3 ML3	RECs AUDA-NEPAD AMA	2025/26 2026-2030	- 1,000,000
Goal 7: Improve supply chains and market access for Priority Medical Products.					
1. Establish regional market data collection programs (manufacturing, import, distribution)	- Regional market data programs. - Advocate for all countries to the declaration of import products mandatory	-No. of countries reporting to regional market data programs	RECs	2027	1,500,000
2. Collaborate with RECs on pooled procurement	- - Distribution policies and costs.	- Market share of local productions in the regional market	RECS	2027	2,000,000

mechanisms/ Regional distribution networks		-No. Distribution hubs operational and pricing structure Harmonized distribution policies			
Cross-cutting objective: Foster partnerships and collaboration for regional manufacturing of priority Medical products					
1. Facilitate and promote PPPs to governments, academia	- PPPs with governments, academia development partners	- No, of partnerships and collaborations	AUDA-NEPAD/ RECs	2025-2030	-

4.3 Intervention timelines

Intervention	Results measure	Responsible entity	Timeline
Objective 1: Secure political commitment and policy support to drive the development of a sustainable African pharmaceutical industry.			
1. Establish high-level political advocacy and dialogue	Stakeholder mapping conducted	AUDA-NEPAD	2025
	Stakeholder engagement framework developed		2025
	AU Council of Ministers and Heads of State endorse Priority list		2025-2030
2. Integrate regional manufacturing priorities into national policies and development plans	Assessment of extent to which countries have integrated regional priorities into national policies/ plans	RECs	2025
	Countries adapt regional priorities into national policies/ plans		2025-2030
3. Secure commitment for regional manufacturing from	Collaborations with private sector eg FAPMA and Civil society organisations	AUDA-NEPAD/ RECs	2025-2030

major regional and global initiatives	Commitments secured from regional and global initiatives		
4. Establish PMPA Secretariat to drive communication and advocacy.	PMPA Coordinator in place	AUDA-NEPAD	2025
	PMPA Governance structures operational		2025-2030
	Publish monthly/quarterly bulletins/ newsletters		2025-2030
Objective 2: Develop and implement policies to promote local production of 24 priority medical products.			
1. Formulate and promote coherent multisectoral policies for local manufacturing on the continent	Adopt the Compendium of Good Pharmaceutical Polices Guidelines and Practices.	AUDA-NEPAD	2025
	- Support countries to develop/ integrate policies on local production	AUDA-NEPAD/ RECs	2025-2030
2. Strengthen IP frameworks to support innovation and local production	- Map countries with IP laws and have utilized them to foster local production	AUDA-NEPAD/ RECS	2025-26
	- Support countries to utilize IP for innovation		2025-2030

3. Implement policy reforms to streamline approval processes for locally manufactured products	- Assess regional policies and best practices on approval processes for locally manufactured products	AUDA-NEPAD/ RECS	2025/6
	- Meetings with national policies to advocate for policy reforms		2026-2027
Objective 3: Strengthen workforce for local pharmaceutical production of priority medical products.			
1. Define a comprehensive list of skills required across the pharmaceutical manufacturing value chain for priority medical products	Assessment report	AUDA-NEPAD/ RECS	2025
1. Assess and designate regional centres for excellence (RCEs) for priority medical products manufacturing training	- Assessment to determine RCEs for training	AUDA-NEPAD/ RECS	2025/6
	- Designate RCEs for training		2026
	- Set up training collaborations between industry and academia		2026-2030

2. Development and implement national, regional and continental training programme focused on priority medical products manufacturing	Establish platform for information sharing and skills development.	AUDA-NEPAD	2025
	Establish e-Learning platform		2025
3. Facilitate PPP to enhance on-job training and skills development.	- Partner secured for on-job training	AUDA-NEPAD	2025/6
4. Create and implement programs for retentions of skilled professionals	- Assessment gaps and opportunities for HR retention	AUDA-NEPAD	2025/6
	- Develop program for pharma industry HR retention	AUDA-NEPAD	2026
Objective 4: Promote research and development, facilitate technology transfer and innovation to support local production of priority medical products.			
1. Establish collaborative research and development network across Africa	RnD network established	AUDA-NEPAD	2026/7

2. Attract and facilitate technology transfer partnerships between African manufacturers and global medical products manufactures	Technology transfer partnerships negotiated/ established	AUDA-NEPAD/RECs	2026-2030
3. Establish/ Develop Innovation hubs to support start-ups and SMEs in health product development	- Innovation hubs developed/ established	AUDA-NEPAD/ RECs	2025-2030
4. Strengthen regional quality infrastructure	- Assessment of quality of regional infrastructure that meets international standards.	AUDA-NEPAD/ RECs	2025/6
	- Support quality improvement of regional infrastructure to meet internationally recognized standards		2025-2030
Objective 5: Create a favourable investment climate for local manufacture of priority medical products.			

1. Develop and implement incentive programmes for local and foreign investors	- Map innovative financing mechanisms/ initiatives for local manufacturing.	AUDA-NEPAD	2025/6
	- Develop framework to guide incentives		
2. Strengthen/ establish PPP to mobilize resources for manufacturing infrastructure	- Financing PPPs strengthened/ established	AUDA-NEPAD/ RECs	2025-2030
3. Improve the regulatory and business environment to facilitate investment	- Map/ identify best practices in regulatory and business environment for pharmaceutical investment	AUDA-NEPAD	2025/6
	- Disseminate best practices	AUDA-NEPAD/ RECs	2025-2030
Objective 6: Strengthen and harmonize regulatory systems to create a conducive environment for the pharmaceutical industry in Africa.			

1-Capacity Building Program for National Medicine Regulatory Authorities (NMRAs)	- Adoption of the African Union's framework for the harmonization of pharmaceutical regulation	RECs	2025/26
	- Set up Capacity Building Program for NMRAs	AUDA-NEPAD	2026-2030
Objective 7: Optimize supply chains and market access for priority medical products.			
1. Establish regional market data collection programs (manufacturing, import, distribution)	- Regional market data programs set up.	RECs/AfCTFA	2027
	- Advocate for all countries to the declaration of import products mandatory		
2. Establish Regional Market Access Hubs/ Programs for pharmaceuticals.	- Regional market access hub/ programs set up	RECs/AfCFTA	2027
	- Regional distribution hubs established		
	- Distribution policies and costs harmonised.		

Cross-cutting objective: Foster partnerships and collaboration for regional manufacturing of priority medical products			
1. Establish PPPs with governments, academia development partners and private sector	- PPPs with governments, academia development partners and private sector established	AUDA-NEPAD/ RECs	2025-2030

4.4 Costing of Roadmap

Intervention	Results measure	Responsible entity	Cost (USD)	Total Cost
Objective 1: Secure political commitment and policy support to drive the development of a sustainable African pharmaceutical industry.				
1. Establish high-level political advocacy and dialogue	Stakeholder mapping conducted	AUDA-NEPAD	2,500	
	Stakeholder engagement framework developed		5,000	
	AU Council of Ministers and Heads of State endorse Priority list		1,000,000	
			300,000	
2. Integrate regional manufacturing priorities into national policies and development plans	Assessment of extent to which countries have integrated regional priorities into national policies/ plans	RECs	10,000	
	Countries adapt regional priorities into national policies/ plans		800,000	
3. Secure commitment for regional manufacturing from major	Collaborations with private sector eg FAPMA and Civil society organisations	AUDA-NEPAD/ RECs	500,000	

regional and global initiatives	Commitments secured from regional and global initiatives			
4. Establish PMPA Secretariat to drive communication and advocacy.	PMPA Coordinator in place	AUDA-NEPAD	300,000	
	PMPA Governance structures operational		600,000	
	Publish monthly/quarterly bulletins/ newsletters		300,000	3,817,500
Objective 2: Develop and implement policies to promote local production of 24 priority medical products.				
1. Formulate and promote coherent multisectoral policies for local manufacturing on the continent	Adopt the Compendium of Good Pharmaceutical Polices Guidelines and Practices.	AUDA-NEPAD	200,000	
	- Support countries to develop/ integrate policies on local production	AUDA-NEPAD/ RECs	2,000,000	
2. Strengthen IP frameworks to support innovation and local production	- Map countries with IP laws and have utilized them to foster local production	AUDA-NEPAD/ RECS	10,000	
	- Support countries to utilize IP for innovation		1,000,000	

3. Implement policy reforms to streamline approval processes for locally manufactured products	- Assess regional policies and best practices on approval processes for locally manufactured products	AUDA-NEPAD/ RECS	15,000	
	- Meetings with national policies to advocate for policy reforms		800,000	4,025,000
Objective 3: Strengthen workforce for local pharmaceutical production of priority list of medical products.				
1. Define a comprehensive list of skills required across the pharmaceutical manufacturing value chain for priority medicines	Mapping/ assessment of pharma skills	AUDA-NEPAD/ RECS	10,000	
2. Assess and designate regional centres for excellence (RCEs) for priority medical products manufacturing training	- Assessment to determine RCEs for training	AUDA-NEPAD/ RECS	150,000	
	- Designate RCEs for training		10,000	
	- Set up training collaborations between industry and academia		500,000	

3. Development and implement national, regional and continental training programme focused on medical products manufacturing	Establish platform for information sharing and skills development.	AUDA-NEPAD	50,000	
	Establish e-Learning platform		50,000	
4. Facilitate PPP to enhance on-job training and skills development.	- Partner secured for on-job training	AUDA-NEPAD	20,000	
5. Create and implement programs for retentions of skilled professionals	- Assessment gaps and opportunities for HR retention	AUDA-NEPAD	50,000	
	- Develop program for pharma industry HR retention	AUDA-NEPAD	100,000	940,000
Objective 4: Promote research and development, facilitate technology transfer and innovation to support local production of priority medical products.				
1. Establish collaborative research and development network across Africa	RnD network established	AUDA-NEPAD	20,000	

2. Attract and facilitate technology transfer partnerships between African manufacturers and global medical products manufactures	Technology transfer partnerships negotiated/ established	AUDA-NEPAD/RECs	400,000	
3. Establish/ Develop Innovation hubs to support start-ups and SMEs in health product development	- Innovation hubs developed/ established	AUDA-NEPAD/ RECs	1,000,000	
4. Strengthen regional quality infrastructure	- Assessment of quality of regional infrastructure that meets international standards.	AUDA-NEPAD/ RECs	150,000	
	- Support quality improvement of regional infrastructure to meet internationally recognized standards		3,000,000	4,570,000
Objective 5: Create a favourable investment climate for local manufacture of priority medical products.				

1. Develop and implement incentive programmes for local and foreign investors	- Map innovative financing mechanisms/ initiatives for local manufacturing.	AUDA-NEPAD	20,000	
	- Develop framework to guide incentives		20,000	
2. Strengthen/ establish PPP to mobilize resources for manufacturing infrastructure	- Financing PPPs strengthened/ established	AUDA-NEPAD/ RECs	200,000	
3. Improve the regulatory and business environment to facilitate investment	- Map/ identify best practices in regulatory and business environment for pharmaceutical investment	AUDA-NEPAD	15,000	
	- Disseminate best practices	AUDA-NEPAD/ RECs	50,000	305,000
Objective 6: Strengthen and harmonize regulatory systems to create a conducive environment for the pharmaceutical industry in Africa.				

1-Capacity Building Program for National Medicine Regulatory Authorities (NMRAs)	- Adoption of the African Union's framework for the harmonization of pharmaceutical regulation	RECs	-	
	- Set up Capacity Building Program for NMRAs	AUDA-NEPAD	1,000,000	1,000,000
Objective 7: Optimize supply chains and market access for priority medical products.				
1. Establish regional market data collection programs (manufacturing, import, distribution)	- Regional market data programs set up.	RECs/AfCTFA	1,500,000	
	- Advocate for all countries to the declaration of import products mandatory			
2. Establish Regional Market Access Hubs/ Programs for pharmaceuticals.	- Regional market access hub/ programs set up	RECs/AfCFTA	2,000,000	
	- Regional distribution hubs established			
	- Distribution policies and costs harmonised.			3,500,000
Cross-cutting objective: Foster partnerships and collaboration for regional manufacturing of priority medical products				

1. Establish PPPs with governments, academia development partners and private sector	- PPPs with governments, academia development partners and private sector established	AUDA-NEPAD/ RECs	-	
TOTAL				**18,157,500**

4.5 Roadmap implementation arrangements

AUDA-NEPAD will coordinate the implementation of this Roadmap working in collaboration with stakeholders to improve access to affordable and quality medicines in Africa. The Roadmap will be implemented through the PMPA Coordination framework. The PMPA Secretariat will manage the day-to-day operations, monitor communications with stakeholders, monitor progress, and address challenges. The PMPA Governing Board and Technical Working Groups will oversee the implementation.

Effective implementation of this Roadmap will require concerted efforts and coordination by all stakeholders including countries, RECs, AU bodies, development partners, civil society and the private sector. Our expectation is that this roadmap should be split into smaller roadmaps for specific molecules or groups of commodities based on needs of the different stakeholders. Deep dive feasibility studies will be required for each of the 24 priority medical product molecules to understand value chain from research and development, availability of inputs to available manufacturing plants, volumes produced, market size and any challenges and opportunities.

AUDA-NEPAD will work with key stakeholders to advocate and support the roles shown below:

No	Stakeholder	Roles
1	African Union Institutions: - African Union Commission (AUC) - African Medicines Agency (AMA) - African Continental Free Trade Area (ACFTA) - African Centre for Disease Control and Prevention (Africa CDC)	- To provide strategic guidance, policy direction, and diplomatic support - Harmonise regulatory standards, promote quality assurance - Provide technical assistance and capacity building to NMRAs to improve their efficiency and effectiveness. - Facilitate regional market access - Encourage governments to prioritize procurement of regionally manufactured medicines - Set up regional and international markets - Contribute expertise in public health, disease surveillance, outbreak response Collaborate on manufacturing initiatives
2	RECs	- Develop and support countries to adapt policies and regulations - Ensure regional harmonisation of quality and efficacy standards of priority medical products - Invest in pharmaceutical ecosystem infrastructure including energy, water, transport systems - Develop and harmonise tax incentives to encourage investment - Negotiate favourable trade agreements to facilitate market access
		- Encourage governments to invest in education and training to develop a skilled workforce
3	National governments	- Develop and implement supportive policies and regulations - Ensure quality and efficacy of medicines through adherence to quality, safety, and efficacy standards - Invest in pharmaceutical ecosystem infrastructure including energy, water, transport systems - Provide tax incentives and subsidies to encourage investment - Negotiate favourable trade agreements to facilitate market access - Develop IPR policies that balance innovation and access to affordable medicines - Invest in education and training to develop a skilled workforce - Establish Public-Private Partnerships and encourage collaborations with international organizations.

4	National medicine regulatory agencies (NMRAs)	- Collaborate with other regulatory agencies to harmonize standards and facilitate trade - Develop and enforce quality standards and guidelines for priority medical products - Fasttrack licenses and approvals for manufacturing facilities and priority medical products - Ensure post market surveillance, pharmacovigilance and monitor the market for substandard and falsified medical products
5	Private Sector (coordinated through pharmaceutical manufacturing associations)	- Investment in capital for research, development, and manufacturing facilities for priority medical products - Innovate new products and technologies - Collaborate on regional distribution of products - Logistics companies can improve supply chain efficiency and reduce costs
6	Civil Society Organizations	- Advocate for policies that promote access to affordable medicines - Monitor and evaluate the implementation of the roadmap Provide training and education to healthcare professionals and communities
7	Academia and Research Institutions	- Train skilled professionals to work industry including scientists, engineers, and technicians - Conduct research and development on priority and new medical products - Share knowledge and expertise with industry and policymakers
8	International Organizations and donors European Union, USAID, United Kingdom's Foreign, Commonwealth & Development Office (FCDO), WHO, UNIDO, UNAIDS, Bill & Melinda Gates Foundation, UNITAID, CHAI etc	- Provide technical assistance and capacity building - Advocate for pharmaceutical manufacturing supportive policies - Facilitate knowledge north-south and south-south exchange and collaboration - Provide grants and loans to support projects
9	Financing Institutions World Bank, African Development Bank (AfDB), Afrexim bank, German Development Bank (KfW)	- Provide financial resources and technical assistance for infrastructure development and capacity building - Finance pharmaceutical manufacturing, health infrastructure, and human capital development related projects

4.6 Implementation risks and their mitigation

No	Risk	Degree of Risk	Description	Mitigation
1	Political choice by leaders	High	Heads of State commitments at AU level are sometimes not reflected or followed up in national policies.	Advocacy at AU and consistent follow-up Forge strong partnerships with governments and international organizations
2	Policy inconsistencies	High	Frequent changes in government policies and regulations can create uncertainty and hinder long-term planning	Diversify manufacturing across RECs to reduce reliance on a single market
3	Political instability and conflicts	Low	Civil unrest in a number of African countries disrupts supply chains, damages infrastructure, and deters investment in the region	Develop risk assessment and mitigation plans to address potential political shocks Forge strong partnerships with governments and international organizations to advocate for stable policies and regulatory environments
4	Economic instability	Medium	Unstable foreign exchange rates can impact the cost of raw materials and finished products	Develop risk assessment and mitigation plans for economic shocks Implement financial strategies like hedging to mitigate currency fluctuations
5	Regulatory red tape	Medium	NMRAs are at different levels of capacity (maturity and funding), have varying cooperation, are affected by the politics in various countries and have different standards which complicates regulatory processes and can impact project timelines and costs	Continue with advocacy efforts at regional and country level to harmonize regulations and standards Advocacy with industry stakeholders to streamline regulatory processes and reduce bureaucratic burdens Maintain open and regular communication with NMRAs
6	Funding	Medium	Implementation of the Roadmap will require	Collaboration with stakeholders will be necessary Explore innovative financing mechanisms

7	High interest rates and limited access to affordable credit	Medium	Africa continues to grapple with the highest interest rates which increases the cost of investment/ production and reduces competitiveness	Continue to engage with financing institutions Explore innovative financing mechanisms
8	Inadequate transportation and energy infrastructure	High	This increases costs and limits the efficiency of supply chains	Advocate for investments in infrastructure, including roads, ports, and energy supply Implement advanced supply chain management techniques, such as real-time tracking and inventory management
9	Logistics challenges	High	There are limited distribution networks across the continent	Establish regional distribution hubs Establish strong partnerships with logistics providers to ensure timely and reliable delivery
10	Customs challenges	Medium	Inefficient customs procedures and border controls can lead to delays and disruptions in the movement of goods	Reduce customs and border controls to enable smooth flow of goods
11	Human capital and skills shortages	High	Shortage of skilled professionals, such as chemists, pharmacists, and engineers is worsened by brain drain	Collaborate with international institutions to facilitate technology and knowledge transfer Establish mentorship and coaching programs for development of skills Develop plans for competitive salaries, benefits, and career development opportunities to retain talent

5 ANNEXEs
5.1 Annex 1: Disease burden in RECs

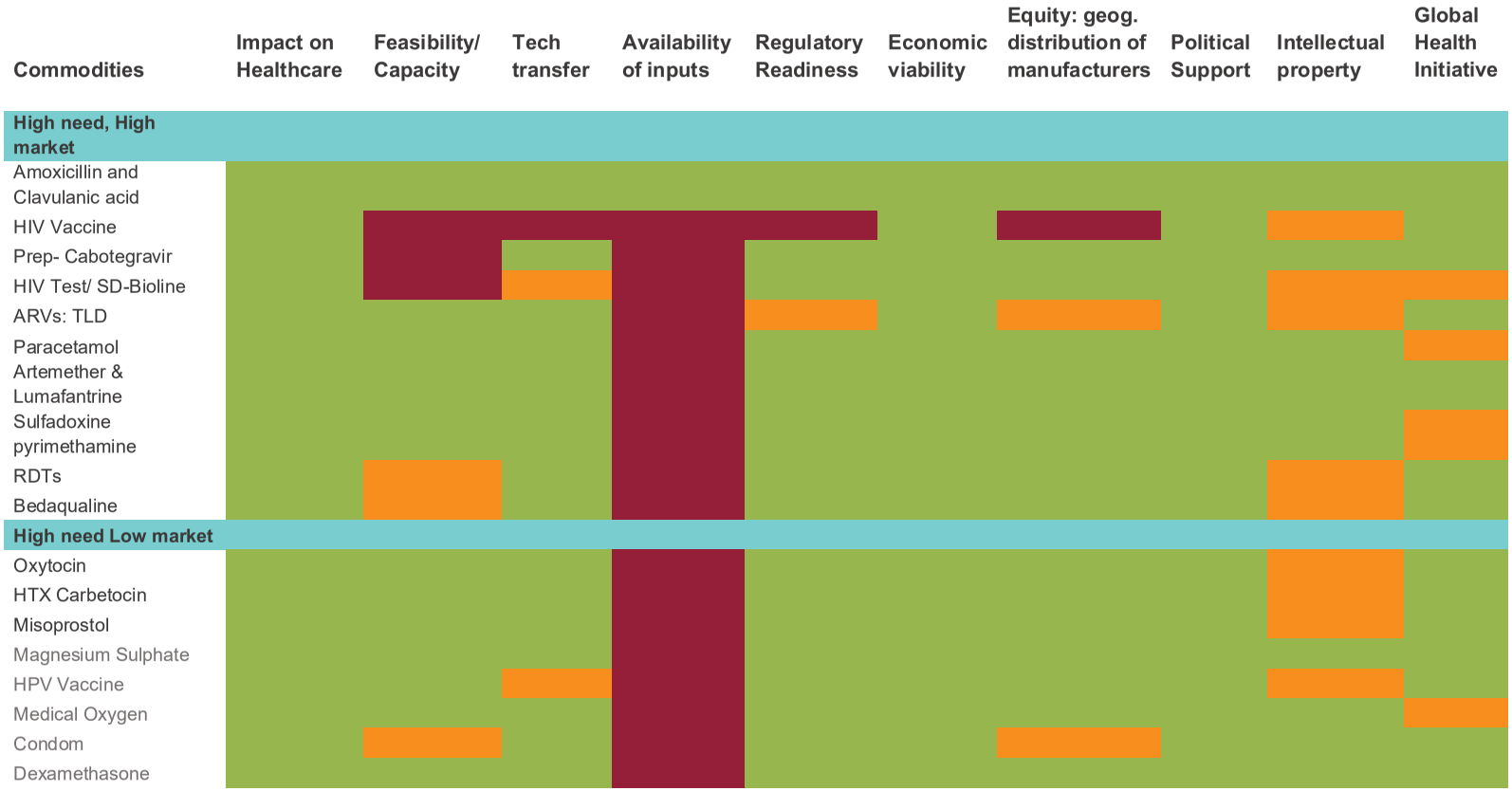
Top 10 Disease Burden in UMA 2021 (no. of countries=6)			
Disease Burden	**Count of Disease Burden**	**Top 10 Disease Burden in SADC 2021 (no. of countries =16)**	
Ischaemic heart disease	5	**Disease Burden**	**Count of Disease Burden**
Stroke	5	Stroke	16
Congenital anomalies	5	Lower respiratory infections	16
Preterm birth complications	4	Preterm birth complications	14
Back and neck pain	4	Diarrhoeal diseases	14
Road injury	4	Tuberculosis	13
Diabetes mellitus	4	Birth asphyxia and birth trauma	12
Depressive disorders	4	HIV/AIDS	11
Anxiety disorders	3	Road injury	9
Birth asphyxia and birth trauma	2	Congenital anomalies	8
Lower respiratory infections	1	Malaria	7
Kidney diseases	1	Diabetes mellitus	6
Malaria	1		
Maternal conditions	1		
Diarrhoeal diseases	1		

Top 10 disease burden in ECOWAS 2021 (no. of countries =15)			
Disease Burden	**Count of Disease Burden**	**Top 10 disease burden in CSSS 2021 (no. of countries =24)**	
Preterm birth complications	15	**Disease Burden**	**Count of Disease Burden**
Lower respiratory infections	15	Preterm birth complications	23
Diarrhoeal diseases	14	Lower respiratory infections	21
Birth asphyxia and birth trauma	14	Birth asphyxia and birth trauma	20
Malaria	13	Diarrhoeal diseases	20
Road injury	12	Stroke	19
Stroke	12	Congenital anomalies	18
HIV/AIDS	11	Road injury	16
Congenital anomalies	11		
Tuberculosis	8	Malaria	15
		HIV/AIDS	11
Meningitis	4	Ischaemic heart disease	11
Ischaemic heart disease	3	Tuberculosis	10
Neonatal sepsis and infections	2	Diabetes mellitus	6

Top 10 disease burden in COMESA 2021 (no. of countries =21)			
Disease Burden	**Count of Disease Burden**	**Top 10 disease burden in ECCAS 2021 (no. of countries =11)**	
Preterm birth complications	19	**Disease Burden**	**Count of Disease Burden**
Lower respiratory infections	19	Lower respiratory infections	11
Stroke	18	Preterm birth complications	11
		Malaria	10
Diarrhoeal diseases	16	Birth asphyxia and birth trauma	10
Congenital anomalies	15	Tuberculosis	10
Birth asphyxia and birth trauma	14	Diarrhoeal diseases	9
Tuberculosis	12	Stroke	8
Ischaemic heart disease	11		
Road injury	9	HIV/AIDS	7
Malaria	9	Congenital anomalies	5
HIV/AIDS	8	Road injury	4
Diabetes mellitus	8	Ischaemic heart disease	4
Depressive disorders	6	Depressive disorders	3
		Cirrhosis of the liver	2
		Measles	2

Top 10 disease burden in IGAD 2021 (no. of countries =8)			
Disease Burden	**Count of Disease Burden**	**Top 10 disease burden in EAC 2021 (no. of countries =8)**	
Preterm birth complications	8	**Disease Burden**	**Count of Burden of Disease**
Lower respiratory infections	8	Preterm birth complications	8
Diarrhoeal diseases	8	Birth asphyxia and birth trauma	8
Birth asphyxia and birth trauma	8	Diarrhoeal diseases	8
Tuberculosis	6	Lower respiratory infections	8
		Malaria	7
Congenital anomalies	5	Tuberculosis	7
Stroke	4	Congenital anomalies	6
HIV/AIDS	4	HIV/AIDS	5
Malaria	4	Stroke	4
Road injury	3	Protein-energy malnutrition	3
Ischaemic heart disease	3		
Protein-energy malnutrition	2	Road injury	2
Measles	2	Meningitis	2
Maternal conditions	2	Depressive disorders	2
Meningitis	2	Measles	2
Depressive disorders	1	Maternal conditions	2
Interpersonal violence	1	Interpersonal violence	1
Cirrhosis of the liver	1	Cirrhosis of the liver	1
Diabetes mellitus	1	Ischaemic heart disease	1
Meningitis	2	Measles	2
Depressive disorders	1	Maternal conditions	2
Interpersonal violence	1	Interpersonal violence	1
Cirrhosis of the liver	1	Cirrhosis of the liver	1
Diabetes mellitus	1	Ischaemic heart disease	1

5.2 Annex II: Hit map showing considerations for selection of priority medical products




Rotavirus Vaccines
ORS and Zinc
Growing need high market
Amlodipine
Perindopril
Acetylsalicyclic acid
Valsartan
Ramipril
Atorvastatin
Bisoprolol
Verapamil
Atenolol
Glyceryl trinitrate
Enalapril
Carvedilol
Losartan
Metformin
Gliclazide
Vildagliptin
Insulin
Glucometer
Strips
Blood substitutes
IV Fluids
Chemotherapy
Growing need low market
Hydroxyurea
Diazepam
Amitryptline
Low need high market
Furosemide
Hep B Vaccine
Low need low market
Praziquantel

6. Bibliography

[1] United Nations, 2024 Revision of World Population Prospects https://population.un.org/wpp/ Accessed 12-8-2024

[2] United Nations Department of Economic and Social Affairs, Population Division (2022). World Population Prospects 2022: Summary of Results. UN DESA/POP/2022/TR/NO. 3.

[3] Potts, D., 2019. What's driving Africa's population growth. And what can change it. The Conversation. 17 November 2019). https://theconversation.com/whats-driving-africas-population-growth-and-what-can-change-it-126362 Accessed 12-8-2024

[4] World Bank IFC, 2007. The Business of Healthcare in Africa https://documents.worldbank.org/en/publication/documents-reports/documentdetail/878891468002994639/The-business-of-health-in-Africa-partnering-with-the-private-sector-to-improve-peoples-lives Accessed 12-8-2024

[5] Africa Centres for Disease Control and Prevention Strategy at a Glance (2017-2021) https://africacdc.org/download/africa-centres-for-disease-control-and-prevention-strategy-at-a-glance/ Accessed 12-08-2024

[6] Max Roser, Hannah Ritchie and Fiona Spooner (2021) - "Burden of Disease" Published online at OurWorldInData.org. Retrieved from: 'https://ourworldindata.org/burden-of-disease' [Online Resource] Accessed 12-8-2024

[7] World Bank Group, 2007 https://documents.worldbank.org/en/publication/documents-reports/documentdetail/732761468779449524/The-World-Bank-annual-report-2007

[8] World Malaria Report 2023 https://www.who.int/publications/i/item/9789240086173

[9] World Malaria Report 2023 https://www.who.int/publications/i/item/9789240086173

[10] World Malaria Report 2023 https://www.who.int/publications/i/item/9789240086173

[11] WHO | Regional Office for Africa. Tuberculosis

https://www.afro.who.int/news/rate-tb-diagnosis-treatment-africa-increasing#:~:text=Globally%20TB%20continues%20to%20claim,000%20lives%20lost%20in%202022.

[12] Gouda HN, Charlson F, Sorsdahl K, et al. Burden of non-communicable diseases in sub-Saharan Africa, 1990-2017: results from the global burden of disease study 2017. Lancet Glob Health 2019;7:e1375–87.doi:10.1016/S2214-109X(19)30374-2pmid:http://www.ncbi.nlm.nih.gov/pubmed/31537368

[13] Bowman B, Seedat M, Duncan N, et al. Violence and Injuries. In: Jamison DT, Feachem RG, Makgoba MW, et al., editors. Disease and Mortality in Sub-Saharan Africa. 2nd edition. Washington (DC): The International Bank for Reconstruction and Development / The World Bank; 2006. Chapter 24. Available from: https://www.ncbi.nlm.nih.gov/books/NBK2308/

[14] World Economic Forum https://www.weforum.org/agenda/2019/02/death-rates-from-traffic-accidents-are-higher-in-africa-than-anywhere-else/#:~:text=Death%20rates%20from%20traffic%20accidents,anywhere%20else%20%7C%20World%20Economic%20Forum

[15]Africa Centres for Disease Control and Prevention Strategy at a Glance (2017-2021) https://africacdc.org/download/africa-centres-for-disease-control-and-prevention-strategy-at-a-glance/

[16] United Nations. (2024, August 15). WHO raises response to mpox outbreak in Africa to highest level. UN News. https://news.un.org/en/story/2024/08/1152956

[17] Michael Conway, Tania Holt, Tania Holt & Sun., I.Y. (2019). Should Sub-Saharan Africa make its own drugs? https://www.mckinsey.com/industries/public-and-social-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs

[18] Bright B, Babalola CP, Sam-Agudu NA, Onyeaghala AA, Olatunji A, Aduh U, Sobande PO, Crowell TA, Tebeje YK, Phillip S, Ndembi N, Folayan MO. COVID-19 preparedness: capacity to manufacture vaccines, therapeutics and diagnostics in sub-Saharan Africa. Global Health. 2021;17(1):24.

[19] Michael Conway, Tania Holt, Tania Holt & Sun., I.Y. (2019). Should Sub-Saharan Africa make its own drugs? https://www.mckinsey.com/industries/public-and-social-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs

[20] Leo Holtz. Figure of the week: Africa's trade in pharmaceuticals. Commentary, December 9, 2021. https://www.brookings.edu/articles/figure-of-the-week-africas-trade-in-pharmaceuticals/

[21] Purity Wambui. The African Pharmaceutical Manufacturing Industry: Opportunities and challenges for growth. Resilient Futures, Future Africa, 28 November 2022. https://forum.futureafrica.com/the-african-pharmaceutical-manufacturing-industry-opportunities-and-challenges-for-growth/

[22] Expanding pharmaceutical local production in Africa: An idea whose time has come? Author : Oommen C. Kurian

[23] Michael Conway, Tania Holt, Tania Holt & Sun., I.Y. (2019). Should Sub-Saharan Africa make its own drugs? https://www.mckinsey.com/industries/public-and-social-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs

[24] Michael Conway, Tania Holt, Tania Holt & Sun., I.Y. (2019). Should Sub-Saharan Africa make its own drugs? https://www.mckinsey.com/industries/public-and-social-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs

[25] African Development Bank Group. A New Frontier for African Pharmaceutical Manufacturing Industry https://www.afdb.org/en/documents/new-frontier-african-pharmaceutical-manufacturing-industry

[26] Michael Conway, Tania Holt, Tania Holt & Sun., I.Y. (2019). Should sub-Saharan Africa make its own drugs? https://www.mckinsey.com/industries/public-and-social-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs

[27] African Development Bank Group. A New Frontier for African Pharmaceutical Manufacturing Industry https://www.afdb.org/en/documents/new-frontier-african-pharmaceutical-manufacturing-industry

[28] GAVI. Expanding sustainable vaccine manufacturing in Africa: Priorities for Support, November 2022. https://www.gavi.org/sites/default files/document/2022/Gavi-Expanding-Sustainable-Vaccine-Manufacturing-in-Africa-2022.pdf

[29] Purity Wambui. The African Pharmaceutical Manufacturing Industry: Opportunities and challenges for growth. Resilient Futures, Future Africa, 28 November 2022. https://forum.futureafrica.com/the-african-pharmaceutical-manufacturing-industry-opportunities-and-challenges-for-growth/

[30] Afya na Haki. Stakeholder Mapping & Analysis Report: Key Players with Legal and Policy Mandates to Implement and Regulate a Sustainable Pharmaceutical Manufacturing Ecosystem for Africa

[31] Ibid

[32] Wellcome Trust. (2022). Strengthening regulatory systems in low- and middle-income countries: Improving the sustainability of the vaccine innovation ecosystem in Africa. Wellcome. https://cms.wellcome.org/sites/default/files/2022-07/strengthening-regulatory-systems-in-low-and-middle-income-countries-improving-the-sustainability-of-the-vaccine-innovation-ecosystem-in-africa.pdf

[33] Afya na Haki. Stakeholder Mapping & Analysis Report: Key Players with Legal and Policy Mandates to Implement and Regulate a Sustainable Pharmaceutical Manufacturing Ecosystem for Africa

[34] Ndomondo-Sigonda M, Miot J, Naidoo S, Dodoo A, Kaale E. Medicines Regulation in Africa: Current State and Opportunities. Pharmaceut Med. 2017;31(6):383-397. doi: 10.1007/s40290-017-0210-x.

[35] World Health Organization. (2017, May 23). Implementation of the National Strategy and Plan of Action for Pharma (NSPA) in Ethiopia getting momentum. WHO Regional Office for Africa. https://www.afro.who.int/news/implementation-national-strategy-and-plan-action-pharma-nspa-pharma-ethiopia-getting-momentum

[36] Michael Conway, Tania Holt, Tania Holt & Sun., I.Y. (2019). Should sub-Saharan Africa make its own drugs? https://www.mckinsey.com/industries/public-and-social-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs

[37] Ncube, B.M., Dube, A. & Ward, K. Establishment of the African Medicines Agency: progress, challenges and regulatory readiness. J of Pharm Policy and Pract 14, 29 (2021). https://doi.org/10.1186/s40545-020-00281-9

[38] Nayyar GM, Attaran A, Clark JP, Culzoni MJ, Fernandez FM, Herrington JE, Kendall M, Newton PN, Breman JG. Responding to the pandemic of falsified medicines. Am J Trop Med Hyg. 2015;92(6 Suppl):113–118. doi:10.4269/ajtmh.14-0393.

[39] Afya na Haki. Stakeholder Mapping & Analysis Report: Key Players with Legal and Policy Mandates to Implement and Regulate a Sustainable Pharmaceutical Manufacturing Ecosystem for Africa

[40] Afya na Haki. Stakeholder Mapping & Analysis Report: Key Players with Legal and Policy Mandates to Implement and Regulate a Sustainable Pharmaceutical Manufacturing Ecosystem for Africa

[41] Ibid

[42] Ibid

[43] African Union: List of Countries which have signed, ratified/acceded to The Statute Of the Pan African Intellectual Property Organization (PAIPO) 23/03/2022. https://au.int/sites/default/files/treaties/32549-sl-statute_of_the_pan_african_intellectual_property_organization_paipo.pdf

[44] Ozawa S, Evans DR, Bessias S, Haynie DG, Yemeke TT, Laing SK, et al. Prevalence and estimated economic burden of substandard and falsified medicines in low- and middle-income countries: a systematic review and meta-analysis. JAMA Netw Open. 2018;1(4):e181662.

[45] World Health Organization. African Medicines Regulatory Harmonization Initiative (AMRHI): a WHO Concept Paper. WHO Drug Inf. 2008;22(3):18290. http://search.ebscohost.com/login.aspx?direct=true&db=hch&AN=35618550&site=ehost-live.

[46] NEPAD. Justification for the African Union Model Law on medical products regulation and harmonization.

[47] NPCA Agency. First scientific conference on Medicines Regulation in Africa. In Johannesburg; 2013.

[48] Narsai K, Williams A, Mantel-Teeuwisse AK. Impact of regulatory requirements on medicine registration in African countries-perceptions and experiences of pharmaceutical companies in South Africa. South Med Rev. 2012;5(1):31–7.

[49] Ndomondo-Sigonda M, Miot J, Naidoo S, Ambali A, Dodoo A, Mkandawire H. The African Medicines Regulatory Harmonization Initiative: progress to date. Med Res Arch. 2018;6(2). https://journals.ke-i.org/mra/article/view/1668.

[50] Ndomondo-Sigonda M, Miot J, Naidoo S, Dodoo A, Kaale E. Medicines Regulation in Africa: current state and opportunities. Pharm Med. 2017;31(6):383–97.

[51] Ndomondo-Sigonda M, Miot J, Naidoo S, Ambali A, Dodoo A, Mkandawire H. The African Medicines Regulatory Harmonization Initiative: progress to date. Med Res Arch. 2018;6(2). https://journals.ke-i.org/mra/article/view/1668.

[52] Michael Conway, Tania Holt, Tania Holt & Sun., I.Y. (2019). Should sub-Saharan Africa make its own drugs? https://www.mckinsey.com/industries/public-and-social-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs

[53] Ndomondo-Sigonda M, Miot J, Naidoo S, Dodoo A, Kaale E. Medicines Regulation in Africa: Current State and Opportunities. Pharmaceut Med. 2017;31(6):383-397. doi: 10.1007/s40290-017-0210-x.

[54] Afya na Haki. Stakeholder Mapping & Analysis Report: Key Players with Legal and Policy Mandates to Implement and Regulate a Sustainable Pharmaceutical Manufacturing Ecosystem for Africa

[55] Ibid

[56] United Nations Industrial Development Organization (UNIDO). Sector Development Strategy for Pharmaceutical Manufacturing in Zimbabwe 2017-2022

[57] Afya na Haki. Stakeholder Mapping & Analysis Report: Key Players with Legal and Policy Mandates to Implement and Regulate a Sustainable Pharmaceutical Manufacturing Ecosystem for Africa

[58] Goldstein Research. African Pharmaceutical Market Report : 2017-2030 (2023 Edition) (goldsteinresearch.com)

[59] Ncube, B.M., Dube, A. & Ward, K. Establishment of the African Medicines Agency: progress, challenges and regulatory readiness. J of Pharm Policy and Pract 14, 29 (2021). https://doi.org/10.1186/s40545-020-00281-9

[60] Afya na Haki. Stakeholder Mapping & Analysis Report: Key Players with Legal and Policy Mandates to Implement and Regulate a Sustainable Pharmaceutical Manufacturing Ecosystem for Africa

[61] Ncube, B.M., Dube, A. & Ward, K. Establishment of the African Medicines Agency: progress, challenges and regulatory readiness. J of Pharm Policy and Pract **14**, 29 (2021). https://doi.org/10.1186/s40545-020-00281-9

[62] Afya na Haki: Stakeholder Mapping & Analysis Report: Key Players with Legal and Policy Mandates to Implement and Regulate a Sustainable Pharmaceutical Manufacturing Ecosystem for Africa

[63] Mackintosh, M., G. Banda, and J. Tunguhole. "Local production of pharmaceuticals and health system strengthening in Africa." German Health Practice Collection (2017).

[64] Purity Wambui. The African Pharmaceutical Manufacturing Industry: Opportunities and challenges for growth. Resilient Futures, Future Africa, 28 November 2022. https://forum.futureafrica.com/the-african-pharmaceutical-manufacturing-industry-opportunities-and-challenges-for-growth/

[65] Strengthening Pharmaceutical Innovation in Africa https://www.unido.org/sites/default/files/2016-01/COHRED-NEPAD_Strengthening_Pharmaceutical_Innovation_Africa__Report_May_2010_FINALweb_0.pdf

[66] World Economic Forum. (2023, March 28). In Africa's free trade area, investment in pharmaceuticals means impact and profit. https://www.weforum.org/agenda/2023/03/in-africa-s-free-trade-area-investment-in-pharmaceuticals-means-impact-and-profit/

[67] Purity Wambui. The African Pharmaceutical Manufacturing Industry: Opportunities and challenges for growth. Resilient Futures, Future Africa, 28 November 2022.

https://forum.futureafrica.com/the-african-pharmaceutical-manufacturing-industry-opportunities-and-challenges-for-growth/

[68] Paul Adepoju: Boosting Africa's pharma industry through R&D, 02 August 2022. Available at: https://www.nature.com/articles/d44148-022-00111-x

[69] African Alliance. (2022, 17 November). BRILLIANT Consortium. African Alliance. Retrieved July 4, 2024, from https://africanalliance.org.za/brilliant-consortium/

[70] Afya na Haki: Assessment of the Legal, Policy and Operational Environment of Pharmaceutical Manufacturers Associations in Africa

[71] Ogbodum, M. U., Shomuyiwa, D. O., Lucero-Prisno III, D. E., Gutu, C. T., Bouali, H., Bangura, B. N., ... & Samai, M. (2023). African Medicines Agency: How it will change the landscape of medicines in Africa. Public Health Challenges, 2(2), e96.

[72] Chorev, N. (2019). Give and take: Developmental foreign aid and the pharmaceutical industry in East Africa. Princeton University Press.

[73] https://au.int/sites/default/files/pages/32894-file-2001-abuja-declaration.pdf

[74] Bein, M.A., Unlucan, D., Olowu, G. and Kalifa, W., 2017. Healthcare spending and health outcomes: evidence from selected East African countries. African health sciences, 17(1), pp.247-254.

[75] Kibira, D., Asiimwe, C., Muwonge, M., Van den Ham, H.A., Reed, T., Leufkens, H.G. and Mantel-Teeuwisse, A.K., 2021. Donor Commitments and Disbursements for Sexual and Reproductive Health Aid in Kenya, Tanzania, Uganda and Zambia. Frontiers in public health, 9, p.278.

[76] PMPA Business Plan

[77] African Development Bank (2014). https://www.afdb.org/en/news-and-events/revitalizing-africas-pharmaceutical-industry-13289.

[78] https://au.int/agenda2063/sdgs

[79] https://au.int/agenda2063/outcomes

[80] Changula, K., Kajihara, M., Mweene, A.S. and Takada, A. (2014), Ebola and Marburg virus diseases in Africa: Increased risk of outbreaks in previously unaffected areas?. Microbiol Immunol, 58: 483-491. https://doi.org/10.1111/1348-0421.12181

[81] Akande-Sholabi, W., & Adebisi, Y. A. (2020). The impact of COVID-19 pandemic on medicine security in Africa: Nigeria as a case study. The Pan African medical journal, 35(Suppl 2), 73.

[82] Bait, S., Lauria, S. M., & Schiraldi, M. M. (2021). Multi-criteria decision-making model for supporting manufacturing settlements location in Africa after COVID-19. International Journal of Engineering Business Management. https://doi.org/10.1177/18479790211023348

[83] OECD (2020). United Nations Economic Commission for Africa. Africa's response to COVID-19: What roles for trade, manufacturing and intellectual property? Tackling coronavirus (COVID-19) contributing to a global effort, Africa's response to COVID-19.

[84] Binagwaho, A., Mutesi, P., & Mathewos, K. (2021). Bolstering Vaccine Manufacturing Capacity in Africa: A move towards self-sufficiency. Brown J. World Aff., 28, 305.

[85] Ramping Up Vaccine manufacturing in Africa | BCG

[86] https://blogs.worldbank.org/en/arabvoices/dialogue-tunisia-pharmaceutical Accessed 08/12/2024

[87] https://blogs.worldbank.org/en/arabvoices/dialogue-tunisia-pharmaceutical Accessed 08/12/2024

[88] Tunisia Investment Authority. Pharmaceutical Sector Presentation. https://tia.gov.tn/storage/app/media/ARGUMENTAIRES/TIA_TUNISIA_PHARMA/AG%20PHARMA%20ANG.pdf

[89] Ibid

[90] Tunisia Investment Authority. Pharmaceutical Sector Presentation. https://tia.gov.tn/storage/app/media/ARGUMENTAIRES/TIA_TUNISIA_PHARMA/AG%20PHARMA%20ANG.pdf

[91] Tunisia Investment Authority. Pharmaceutical Sector Presentation. https://tia.gov.tn/storage/app/media/ARGUMENTAIRES/TIA_TUNISIA_PHARMA/AG%20PHARMA%20ANG.pdf

[92] Tunisia Investment Authority. Pharmaceutical Sector Presentation. https://tia.gov.tn/storage/app/media/ARGUMENTAIRES/TIA_TUNISIA_PHARMA/AG%20PHARMA%20ANG.pdf

[93] Tunisia Investment Authority. Pharmaceutical Sector Presentation. https://tia.gov.tn/storage/app/media/ARGUMENTAIRES/TIA_TUNISIA_PHARMA/AG%20PHARMA%20ANG.pdf

[94] Tunisia Investment Authority. Pharmaceutical Sector Presentation. https://tia.gov.tn/storage/app/media/ARGUMENTAIRES/TIA_TUNISIA_PHARMA/AG%20PHARMA%20ANG.pdf

[95] Mirza, Zafar. "Thirty years of essential medicines in primary health care." EMHJ-Eastern Mediterranean Health Journal, 14 (Supp.), S74-S81, 2008 (2008).

[96] Pammolli F, Magazzini L, Riccaboni M. The productivity crisis in pharmaceutical R&D. Nat Rev Drug Discov. 2011 Jun;10(6):428-38. doi: 10.1038/nrd3405. PMID: 21629293.

[97] Hardman, J.G., Limbird, L.E. and Gilman, A.G. (2001) Goodman & Gilman's The Pharmacological Basis of Therapeutics. 10th Edition, McGraw-Hill, New York.

[98] Mirza, Zafar. "Thirty years of essential medicines in primary health care." EMHJ-Eastern Mediterranean Health Journal, 14 (Supp.), S74-S81, 2008 (2008).

[99] 25 years of the WHO essential medicines lists: progress and challenges. Laing, Richard et al. The Lancet, Volume 361, Issue 9370, 1723 - 1729

[100] 25 years of the WHO essential medicines lists: progress and challenges. Laing, Richard et al. The Lancet, Volume 361, Issue 9370, 1723 - 1729

[101] Ibid

[102] International Federation of Pharmaceutical Manufacturers Association. Issue paper: the "Essential Drugs" concept—February, 1997. http://www.pharmweb.net/pwmirror/pw9/ifpma/pdfifpma/edl.pdf

[103] 25 years of the WHO essential medicines lists: progress and challenges. Laing, Richard et al. The Lancet, Volume 361, Issue 9370, 1723 – 1729

[104] Ibid

[105] WHO. Procedure to update and disseminate the WHO model list of essential medicines document EB109/8 (Annex). Geneva: World Health Organization, 2002.

[106]WHO. Report on the 12th Expert Committee on the Selection and Use of Essential Medicines. Geneva: World Health Organization, 2002

[107] WHO. Model Lists of essential medicines Geneva, Switzerland: World Health organization, 2020. Available: https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists

[108] Wirtz VJ, Hogerzeil HV, Gray AL, Bigdeli M, de Joncheere CP, Ewen MA, et al. Essential medicines for universal health coverage. Lancet. 2017. January 28;389(10067):403–76. 10.1016/S0140-6736(16)31599-9

[109] WHO. WHO model list of essential medicines: Wikipedia, 2020. Available: https://en.wikipedia.org/wiki/WHO_Model_List_of_ Essential_Medicines

[110] L. Nixdorf, 2014, Pharmaceutical Manufacturing in Ghana: Lessons Learnt for the East African Community, paper presented to FEAPM AGM in Kampala, Uganda

[111] Ibid

[112] Algeria: New Policy in Pharmaceutical Industry https://lexafrica.com/2022/06/algeria-new-policy-in-the-pharmaceutical-industry/#:~:text=Import%20of%20pharmaceutical%20products&text=One%20of%20the%20objectives%20of,euros%20on%20imports%20for%202021. Accessed on 8/12/2024

[113] Ibid

[114] Trade Regime https://www.eac.int/regional-framework/trade-regime

[115] Ministry of Trade, Industry and Cooperatives. (2014). Buy Uganda Build Uganda (BUBU) Policy. Retrieved from: http://mtic.go.ug/wp-content/uploads/2019/08/BUBU.pdf

[116] https://www.who.int/data/gho/data/themes/mortality-and-global-health-estimates/global-health-estimates-leading-causes-of-dalys#:~:text=DALYs%20for%20a%20disease%20or,health%20condition%20in%20a%20population. Accessed 29-7-2024

[117] https://list.essentialmeds.org/

[118] Successful project management with the Traffic Light Method https://parm.com/en/successful-project-management-with-the-traffic-light-method/#:~:text=The%20method%20utilizes%20the%20three,planned%20without%20any%20acute%20issues. Accessed 09/3/2024

[119] CEPI website: Why We Exist, https://cepi.net/?p=98; and Our Portfolio, https://cepi.net/?p=644.

[120] CEPI website: Our Mission to Enable Equitable Access, https://cepi.net/?p=8238.

[121] CEPI, Equitable Access Policy, 20 December 2018, https://cepi.net/wp-content/uploads/2019/01/Equitable-Access-Policy.pdf.

[122] CEPI, CEPI and the African Union Join Forces to Boost African Vaccine R&D and Manufacturing, 13 April 2021, https://cepi.net/?p=7010.

[123] CEPI, Aspen, CEPI and the Bill & Melinda Gates Foundation Expand Commitments to Improve Access to Vaccines in Africa, 12 December 2022, https://cepi.net/?p=9388.

[124] CEPI, CEPI and Institut Pasteur de Dakar Announce 10-Year Partnership to Boost Manufacturing of Affordable Vaccines for the Global South, 19 January 2023, https://cepi.net/?p=9517

[125] Unitaid website: Who We Are, https://unitaid.org/about-us. One of such partners is the Global Fund to fight AIDS, Tuberculosis and Malaria

[126] Unitaid website: Partners, https://unitaid.org/how-we-work/partners.

[127] Dominic Hein, UNICEF Vaccine Industry Consultation (Gavi presentation), 27 September 2022, https://www.unicef.org/supply/media/14071/file/Partner_update_GAVI_Dominic_Hein_2022.pdf.

[128] Gavi, A New Era of Vaccine Manufacturing in Africa, June 2022, https://www.gavi.org/node/116791

[129] https://www.gavi.org/our-alliance/market-shaping/vaccine-innovation-prioritisation-strategy

[130] UN COMMISSION ON LIFE-SAVING COMMODITIES FOR WOMEN AND CHILDREN Commissioners" Report September 2012

[131] [131] https://africacdc.org/download/partnerships-for-african-vaccine-manufacturing-pavm-framework-for-action/ accessed 8-8-2024

[132] https://www.theglobalfund.org/en/sourcing-management/updates/2023-11-21-update-to-evaluation-of-diagnostic-products-african-manufactured-hiv-rapid-tests/

[133] Africa PMPA Business Plan https://au.int/sites/default/files/pages/32895-file-pmpa_business_plan.pdf Accessed 8/15/2024

[134] Africa PMPA Business Plan https://au.int/sites/default/files/pages/32895-file-pmpa_business_plan.pdf Accessed 8/15/2024

[135] The African Pharmaceutical Manufacturing Industry: Opportunities and challenges for growth https://forum.futureafrica.com/the-african-pharmaceutical-manufacturing-industry-opportunities-and-challenges-for-growth/ Accessed 08/16/2024

[136] The African Pharmaceutical Manufacturing Industry: Opportunities and challenges for growth https://forum.futureafrica.com/the-african-pharmaceutical-manufacturing-industry-opportunities-and-challenges-for-growth/ Accessed 08/16/2024

[137] Africa PMPA Business Plan https://au.int/sites/default/files/pages/32895-file-pmpa_business_plan.pdf Accessed 8/15/2024

[138] Africa PMPA Business Plan https://au.int/sites/default/files/pages/32895-file-pmpa_business_plan.pdf Accessed 8/15/2024

[139] Africa PMPA Business Plan https://au.int/sites/default/files/pages/32895-file-pmpa_business_plan.pdf Accessed 8/15/2024

[140] African Development Bank Group. A New Frontier for African Pharmaceutical Manufacturing Industry https://www.afdb.org/en/documents/new-frontier-african-pharmaceutical-manufacturing-industry

[141] Africa PMPA Business Plan https://au.int/sites/default/files/pages/32895-file-pmpa_business_plan.pdf Accessed 8/15/2024

[142] Support to Africa's Pharmaceutical Industry: 2030 Vision and Action Plan AfDB https://www.fondation-merieux.org/wp-content/uploads/2023/06/introducing-pcv-rotavirus-vaccine-2023-day-3-amadou-bassirou-diallo.pdf Accessed 08/15/2024

[143] Support to Africa's Pharmaceutical Industry: 2030 Vision and Action Plan AfDB https://www.fondation-merieux.org/wp-content/uploads/2023/06/introducing-pcv-rotavirus-vaccine-2023-day-3-amadou-bassirou-diallo.pdf Accessed 08/15/2024

[144] Africa PMPA Business Plan https://au.int/sites/default/files/pages/32895-file-pmpa_business_plan.pdf Accessed 8/15/2024

[145] Ibid

[146] Ibid

[147] The African Pharmaceutical Manufacturing Industry: Opportunities and challenges for growth https://forum.futureafrica.com/the-african-pharmaceutical-manufacturing-industry-opportunities-and-challenges-for-growth/ Accessed 08/16/2024

[148] Mackintosh, M., Chaudhuri, S., Mohamed, N., Wangwe, S., Ngoma, T., Manduku, V. (2024). Oncology Drug Production in Sub-Saharan Africa: The Challenge and Opportunity, with Evidence from India. In: Banda, G., Mackintosh, M., Njeru, M.K., Makene, F.S., Srinivas, S. (eds) Cancer Care in Pandemic Times: Building Inclusive Local Health Security in Africa and India. International Political Economy Series. Palgrave Macmillan, Cham. https://doi.org/10.1007/978-3-031-44123-3_8

[149] https://canceralliance.org.za/wp-content/uploads/2021/06/Access-to-Cancer-Medicines-SA-April-2021-v3.pdf Accessed 08/14/2024

[150] https://www.evapharma.com/newsroom/oncology-experts-hail-moves-to-manufacture-cancer-treatments-locally--29 Accessed 08/14/2024

[151] https://www.evapharma.com/science-medicine/products/lenalidomide-10-mg-371

[152] https://qualitymatters.usp.org/producing-maternal-health-supplies-sub-saharan-africa

[153] Identifying Potential African Manufacturers of Amoxicillin DT and Beta-Lactam Products to Expand Access to Quality-Assured Products. Eliangiringa Kaale, Vicky Manyanga and Rafael Shedafa Muhimbili University of Health and Allied Sciences. Scientific Conference on Medicines Regulation in Africa 5-7 December 2023

[154] https://www.who.int/news-room/fact-sheets/detail/malaria

[155] Malaria chemoprevention Preferred product characteristics WHO

[156] Say, Lale et al. “Global causes of maternal death: a WHO systematic analysis,” The Lancet, 05 May 2014, https://www.thelancet.com/journals/langlo/article/ PIIS2214-109X (14)70227-X/fulltext.

[157] https://www.mmv.org/mmv-pipeline-antimalarial-drugs/sulfadoxine pyrimethamine#:~:text=Full%20course%20of%20IPTp%2DSP,and%20neonatal%20mortality%20by%2031%25.

[158] “The Lusaka Agenda: Conclusions of the Future of Global Health Initiatives process”, Future of Global Health Initiatives co-chairs, accessed 18 April 2024https://d2nhv1us8wflpq.cloudfront.net/prod/uploads/2023/12/Lusaka-Agenda.pdf

[159] A delay in the clearance of malaria parasites from the bloodstream following treatment with an ACT. As a result, the artemisinin compound is less effective

in clearing all parasites within a 3-day period among patients who are infected with artemisinin partially resistant strains of malaria

[160] “Strategy to respond to antimalarial drug resistance in Africa”, WHO, accessed 18 April 2024, https://www.who.int/publications/i/item/9789240060265

[161] “Strategy to respond to antimalarial drug resistance in Africa”, WHO, accessed 18 April 2024, https://www.who.int/publications/i/item/9789240060265

[162] Manufacturing Landscape Assessment for Maternal Health Supplies in sub-Saharan Africa. U.S. Pharmacopeial Convention, Reproductive Health Supplies Coalition. March 2024.

[163] https://unitaid.org/assets/Unitaid-and-medical-oxygen.pdf

[164] Sources: (1) B. Dadonaite, OurWorldInData.org, 2018. (2) R. Ahmed et al., “The epidemiology of noncommunicable respiratory disease in SSA, the Middle East, and North Africa,” Forum of International Respiratory Societies, 2017. (3) Forum of International Respiratory Societies, “The Global Impact of Respiratory Disease,” European Respiratory Society, 2017. (4) J.B. Grin et al., “Evaluating WHO-Recommended Interventions for Preterm Birth: A Mathematical Model of the Potential Reduction of Preterm Mortality in Sub-Saharan Africa,” World Health Organization, 2019.

[165] Nkengasong, J, et al (2022) “Two years of COVID-19 in Africa: lessons for the world. Africa urgently needs to guarantee its own health security,” Nature, 3 January. Available at https://www.nature.com/articles/d41586-021-03821-8.

[166] The Government of Malawi released their National Oxygen Ecosystem Roadmap for 2021-2026 in December 2021 and called for $US75 million to implement it over five years.

[167] More recently, a variation of the PSA process known as vacuum swing adsorption (VSA) has also emerged as a high-potential option. For the purposes of this discussion, we use “PSA” to refer to both PSA and VSA

[168] Cryogenic air separation plants also produce a number of other industrial gases.

[169] Zinc/ORS Scale-up in Nigeria. CHAI Diarrhea & Pneumonia Working Group June 20, New York https://www.childhealthtaskforce.org/sites/default/files/2019-07/Zinc%20ORS%20Scale-

up%20in%20Nigeria%20Presentation%28Diarrhea%20and%20Pneumonia%20Working%20Group%2C%20CHAI%2C%202013%29.pdf Accessed 15-08-2024

[170] UNICEF Supply Division, Oral Rehydration Salts and Zinc - Market and Supply Update September 2022 https://www.unicef.org/supply/media/13851/file/ORS-and-Zinc-Market-Supply-Update-September-2022.pdf Accessed 1-9-2024

[171] Troeger C, Khalil IA, Rao PC, et al.. Rotavirus vaccination and the global burden of rotavirus diarrhea among children younger than 5 years. JAMA Pediatr 2018; 172:958–65.

[172] WHO Regional Office for Africa Regional Committee for Africa Sickle-cell disease: a strategy for the WHO African region https://apps.who.int/iris/handle/10665/1682

[173] WHO Regional Office for Africa Regional Committee for Africa Sickle-cell disease: a strategy for the WHO African region https://apps.who.int/iris/handle/10665/1682

[174] Weatherall DJ et al. Inherited disorders of hemoglobin. In: Disease Control Priorities in Developing Countries. Jamison D et al. New York, Oxford University Press and the World Bank, 2006, 663-80.

[175] Rahimy MC et al. Effect of a comprehensive clinical care program on disease course in severely ill children with sickle cell anemia in a sub-Saharan Africa setting. Blood, 2003, 102(3):834–38.

[176] https://www.gov.za/speeches/media-statement-commissioner-investigation-manufacturers-cancer-drugs-13-jun-2017-0000 consulted 15/08/2022

[177] CHAI and ACS announce agreement to expand Cancer Access Partnership

https://www.clintonhealthaccess.org/chai-and-acs-announce-agreement-to-expand-cancer-access-partnership/. Accessed 2-9-2024

[178] European Commission, Questions and Answers - Antitrust: Aspen https://ec.europa.eu/commission/presscorner/detail/en/QANDA_21_521 Accessed 2-9-2024

[179] Cancer Care in Pandemic Times Building Inclusive Local Health Security in Africa and India https://link.springer.com/book/10.1007/978-3-031-44123-3 Accessed 1-9-2024

[180] Medicines Patent Pool. Prioritisation of medicines for in-licensing by the Medicines Patent Pool-2021, July, 2022, https://medicinespatentpool.org/what-we-do/prioritising-medicines-for-licensing

[181] Manufacturing condoms in Africa: an urgent health and economic priority

Calendar; 09 November 2018 https://esaro.unfpa.org/en/news/manufacturing-condoms-africa-urgent-health-and-economic-priority Accessed 04/09/2024

[182] Manufacturing condoms in Africa: an urgent health and economic priority

Calendar; 09 November 2018 https://esaro.unfpa.org/en/news/manufacturing-condoms-africa-urgent-health-and-economic-priority Accessed 04/09/2024

[183] Manufacturing condoms in Africa: an urgent health and economic priority

Calendar; 09 November 2018 https://esaro.unfpa.org/en/news/manufacturing-condoms-africa-urgent-health-and-economic-priority Accessed 04/09/2024

[184] World Malaria Report 2023 https://www.who.int/publications/i/item/9789240086173

[185] World Malaria Report 2023 https://www.who.int/publications/i/item/9789240086173

[186] Hassan, A. O., Oso, O. V., Obeagu, E. I., & Adeyemo, A. T. (2022). MALARIA VACCINE: PROSPECTS AND CHALLENGES. Madonna University Journal of Medicine and Health Sciences ISSN: 2814-3035, 2(2), 22-40. Retrieved from http://madonnauniversity.edu.ng/journals/index.php/medicine/article/view/64

[187] Malaria vaccine implementation programme https://www.who.int/initiatives/malaria-vaccine-implementation-programme Accessed 09/04/2024

[188] iAHO Fact Sheet https://files.aho.afro.who.int/afahobckpcontainer/production/files/iAHO_Hepatitis_Regional_Factsheet_ENG.pdf Accessed 09/04/2024

[189] Schemm Y. Africa Doubles Research Output, Moves toward Knowledge-based Economy - What Factors are Driving the Increase in Scientific Research being Conducted by African Scientists? *Research Trends* 2013;35:1–4.

[190] Nwaka S, Ilunga TB, Da Silva JS, et al.. Developing ANDI: a novel approach to health product R&D in Africa. *PLoS Med* 2010;7:e1000293 10.1371/journal.pmed.1000293

[191] African research foundation partners with international pharmaceutical industry to strengthen capacity for health innovation in Africa By IFPMA https://www.ifpma.org/news/african-research-foundation-partners-with-international-pharmaceutical-industry-to-strengthen-capacity-for-health-innovation-in-africa/ Accessed 09/04/2024

[192] African Union and Africa CDC. (2021). Discussion paper on Africa's Vaccine Manufacturing for Health Security at the Conference on Expanding Africa's Vaccine Manufacturing: https://africacdc.org/event/virtualconference-expanding-africas-vaccine-manufacturing/.

[193] African Union and Africa CDC. (2021). Discussion paper on Africa's Vaccine Manufacturing for Health Security at the Conference on Expanding Africa's Vaccine Manufacturing: https://africacdc.org/event/virtualconference-expanding-africas-vaccine-manufacturing/.

[194] Michael Conway, Tania Holt, Tania Holt & Sun., I.Y. (2019). Should Sub-Saharan Africa make its own drugs? https://www.mckinsey.com/industries/public-and-social-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs

[195] Michael Conway, Tania Holt, Tania Holt & Sun., I.Y. (2019). Should Sub-Saharan Africa make its own drugs? https://www.mckinsey.com/industries/public-and-social-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs

[196] UNIDO, 2019. Pharmaceutical industry in sub-Saharan Africa. A guide for promoting local pharmaceutical production in Africa. https://www.unido.org/sites/default/files/files/2019-01/Boosting_Pharmaceutical_Production.pdf. accessed 29-8-2024

[197] UNDP, 2013. Promoting Local Pharmaceutical Production in Uganda. Challenges facing local pharmaceutical firms. https://info.undp.org/docs/pdc/Documents/UGA/Local%20pharmaceutical%20production%20challenges%20(1)-1.pdf. Accessed 18-8-24

[198] Support to Africa's Pharmaceutical Industry: 2030 Vision and Action Plan AfDB https://www.fondation-merieux.org/wp-content/uploads/2023/06/introducing-pcv-rotavirus-vaccine-2023-day-3-amadou-bassirou-diallo.pdf Accessed 08/15/2024

[199] African Union: List of Countries which have signed, ratified/acceded to The Statute Of the Pan African Intellectual Property Organization (PAIPO) 23/03/2022. https://au.int/sites/default/files/treaties/32549-sl-statute_of_the_pan_african_intellectual_property_organization_paipo.pdf

[200] Nayyar GM, Attaran A, Clark JP, Culzoni MJ, Fernandez FM, Herrington JE, Kendall M, Newton PN, Breman JG. Responding to the pandemic of falsified medicines. Am J Trop Med Hyg. 2015;92(6 Suppl):113–118. doi:10.4269/ajtmh.14-0393.

[201] Ibid

[202] Ndomondo-Sigonda M, Miot J, Naidoo S, Dodoo A, Kaale E. Medicines Regulation in Africa: Current State and Opportunities. Pharmaceut Med. 2017;31(6):383-397. doi: 10.1007/s40290-017-0210-x.

[203] Ifeagwu SC, Yang JC, Parkes-Ratanshi R, Brayne C. Health financing for universal health coverage in sub-Saharan Africa: a systematic review. *Glob Health Res Policy*. 2021. Mar 1;6(1):8. 10.1186/s41256-021-00190-7

[204] Nwoko F, Okeke U, Effiong U. Drivers and solutions for universal health coverage in Africa. Johannesburg: Africa Portal; 2020. Available from: https://www.africaportal.org/features/drivers-and-solutions-universal-health-coverage-africa/

[205] CBHI Scheme https://www.rssb.rw/scheme/cbhi-scheme Accessed 04/09/2024

NOTES:

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